PRESSURIZED WATER REACTOR OWNERS GROUP

PWROG
PWR Owners Group

PWROG-22010-NP
Revision 0

WESTINGHOUSE NON-PROPRIETARY CLASS 3

Risk Assessment Process for Review of Topical Reports (RAPTR)

Risk Management Committee

PA-RMSC-1835, Revision 1

October 2022

Westinghouse

PWROG-22010-NP
Revision 0

Risk Assessment Process for Review of Topical Reports (RAPTR)

PA-RMSC-1835, Revision 1, Revision 1

Reed LaBarge*
Risk Analysis

Andrea Maioli*
Safety Analysis, Risk Applications & Licensing

Jennifer Meneely*
Licensing

October 2022

Reviewer: James Andrachek*
PWR Owners Group PMO

Approved: Amanda Charleroy*, Manager
Risk Analysis

Approved: Damian Mirizio*, Program Director
PWR Owners Group PMO

This document may contain technical data subject to the export control laws of the United States. In the event that this document does contain such information, the Recipient's acceptance of this document constitutes agreement that this information in document form (or any other medium), including any attachments and exhibits hereto, shall not be exported, released or disclosed to foreign persons whether in the United States or abroad by recipient except in compliance with all U.S. export control regulations. Recipient shall include this notice with any reproduced or excerpted portion of this document or any document derived from, based on, incorporating, using or relying on the information contained in this document.

*Electronically approved records are authenticated in the electronic document management system.

Westinghouse Electric Company LLC
1000 Westinghouse Drive
Cranberry Township, PA 16066, USA

© 2022 Westinghouse Electric Company LLC
All Rights Reserved

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

Record of Revisions

Rev.	Date	Revision Description
0-A	2022-10-19	Draft for discussion with NRC
0	See PRIME	No technical changes. Document re-issues as Rev. 0 to be docketed

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

ACKNOWLEDGEMENTS

This report was developed and funded by the PWR Owners Group under the leadership of the participating utility representatives of the Risk Management Committee. The author would like to thank the following people and/or organizations for their valuable contributions to this report:

Brad Dolan (TVA, PWROG, RMC Chairman)

Drew Richards (STPNOC, PWROG LC Chairman)

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

LEGAL NOTICE

This report was prepared as an account of work performed by Westinghouse Electric Company LLC. Neither Westinghouse Electric Company LLC, nor any person acting on its behalf:

1. Makes any warranty or representation, express or implied including the warranties of fitness for a particular purpose or merchantability, with respect to the accuracy, completeness, or usefulness of the information contained in this report, or that the use of any information, apparatus, method, or process disclosed in this report may not infringe privately owned rights; or

2. Assumes any liabilities with respect to the use of, or for damages resulting from the use of, any information, apparatus, method, or process disclosed in this report.

COPYRIGHT NOTICE

This report has been prepared by Westinghouse Electric Company LLC and bears a Westinghouse Electric Company copyright notice. Information in this report is the property of and contains copyright material owned by Westinghouse Electric Company LLC and/or its affiliates, subcontractors and/or suppliers. It is transmitted to you in confidence and trust, and you agree to treat this document and the material contained therein in strict accordance with the terms and conditions of the agreement under which it was provided to you.

As a participating member of this task, you are permitted to make the number of copies of the information contained in this report that are necessary for your internal use in connection with your implementation of the report results for your plant(s) in your normal conduct of business. Should implementation of this report involve a third party, you are permitted to make the number of copies of the information contained in this report that are necessary for the third party's use in supporting your implementation at your plant(s) in your normal conduct of business if you have received the prior, written consent of Westinghouse Electric Company LLC to transmit this information to a third party or parties. All copies made by you must include the copyright notice in all instances.

DISTRIBUTION NOTICE

This report was prepared for the PWR Owners Group. This Distribution Notice is intended to establish guidance for access to this information. This report (including proprietary and non-proprietary versions) is not to be provided to any individual or organization outside of the PWR Owners Group program participants without prior written approval of the PWR Owners Group Program Management Office. However, prior written approval is not required for program participants to provide copies of Class 3 Non-Proprietary reports to third parties that are supporting implementation at their plant, and for submittals to the NRC.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
United States Member Participation* for PA-RMSC-1835, Revision 1

Utility Member	Plant Site(s)	Participant	
		Yes	No
Ameren Missouri	Callaway (W)	X	
American Electric Power	D.C. Cook 1 & 2 (W)	X	
Arizona Public Service	Palo Verde Unit 1, 2, & 3 (CE)	X	
Constellation Generation Co. LLC	Braidwood 1 & 2 (W)	X	
	Byron 1 & 2 (W)	X	
	Calvert Cliffs 1 & 2 (CE)	X	
	Ginna (W)	X	
Dominion Energy	Millstone 2 (CE)	X	
	Millstone 3 (W)	X	
	North Anna 1 & 2 (W)	X	
	Surry 1 & 2 (W)	X	
	V.C. Summer (W)	X	
Duke Energy Carolinas	Catawba 1 & 2 (W)	X	
	McGuire 1 & 2 (W)	X	
	Oconee 1, 2, & 3 (B&W)	X	
Duke Energy Progress	Robinson 2 (W)	X	
	Shearon Harris (W)	X	
Entergy Operations South	Arkansas 1 (B&W)	X	
	Arkansas 2 (CE)	X	
	Waterford 3 (CE)	X	
Evergy	Wolf Creek (W)	X	
Energy Harbor	Beaver Valley 1 & 2 (W)	X	
	Davis-Besse (B&W)	X	
Florida Power & Light \ NextEra	St. Lucie 1 & 2 (CE)	X	
	Turkey Point 3 & 4 (W)	X	
	Seabrook (W)	X	
	Pt. Beach 1 & 2 (W)	X	
Luminant Power	Comanche Peak 1 & 2 (W)	X	
Pacific Gas & Electric	Diablo Canyon 1 & 2 (W)	X	

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
United States Member Participation* for PA-RMSC-1835, Revision 1

Utility Member	Plant Site(s)	Participant	
		Yes	No
PSEG – Nuclear	Salem 1 & 2 (W)	X	
So. Texas Project Nuclear Operating Co.	South Texas Project 1 & 2 (W)	X	
Southern Nuclear Operating Co.	Farley 1 & 2 (W)	X	
	Vogtle 1 & 2 (W)	X	
	Vogtle 3 & 4 (W)	X	
Tennessee Valley Authority	Sequoyah 1 & 2 (W)	X	
	Watts Bar 1 & 2 (W)	X	
Xcel Energy	Prairie Island 1 & 2 (W)	X	

* Project participants as of the date the final deliverable was completed. On occasion, additional members will join a project. Please contact the PWR Owners Group Program Management Office to verify participation before sending this document to participants not listed above.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
International Member Participation* for PA-RMSC-1835, Revision 1

Utility Member	Plant Site(s)	Participant	
		Yes	No
Asociación Nuclear Ascó-Vandellòs	Asco 1 & 2 (W)	X	
	Vandellos 2 (W)	X	
Centrales Nucleares Almaraz-Trillo	Almaraz 1 & 2 (W)	X	
CEZ**	Temelin		X
EDF Energy	Sizewell B (W)	X	
Electrabel	Doel 1, 2 & 4 (W)	X	
	Tihange 1 & 3 (W)	X	
Electricite de France	56 Units	X	
Elektriciteits Produktiemaatschappij Zuid-Nederland	Borssele 1 (Siemens)	X	
Eletronuclear-Eletrobras	Angra 1 (W)	X	
Emirates Nuclear Energy Corporation	Barakah 1 & 2	X	
Hokkaido	Tomari 1, 2 & 3 (MHI)	X	
Japan Atomic Power Company	Tsuruga 2 (MHI)	X	
Kansai Electric Co., LTD	Mihama 3 (W)	X	
	Ohi 3 & 4 (W & MHI)	X	
	Takahama 1, 2, 3 & 4 (W & MHI)	X	
Korea Hydro & Nuclear Power Corp.	Kori 1, 2, 3 & 4 (W)	X	
	Hanbit 1 & 2 (W)	X	
	Hanbit 3, 4, 5 & 6 (CE)	X	
	Hanul 3, 4, 5 & 6 (CE)	X	
Kyushu	Genkai 3 & 4 (MHI)	X	
	Sendai 1 & 2 (MHI)	X	
Nuklearna Electrarna KRSKO	Krsko (W)	X	
Ringhals AB	Ringhals 3 & 4 (W)	X	
Shikoku	Ikata 3 (MHI)	X	
Taiwan Power Co.	Maanshan 1 & 2 (W)	X	

* Project participants as of the date the final deliverable was completed. On occasion, additional members will join a project. Please contact the PWR Owners Group Program Management Office to verify participation before sending this document to participants not listed above.

** I&C Working Group Only

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

TABLE OF CONTENTS

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

LIST OF FIGURES

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

1 INTRODUCTION

The United States Nuclear Regulatory Commission (NRC) issued Temporary Staff Guidance (TSG) for Risk Informed Process for Evaluations (RIPE) (Reference 1), which contains a framework for the streamlined processing of license amendment requests (LARs) and exemption requests. That framework can be expanded to allow issues of minimal safety impact to be addressed generically, and after NRC approval of a Topical Report (TR) that contains a generic risk assessment, to be implemented on a plant-specific basis by referencing the NRC approved TR. This new framework or process is called the Risk Assessment Process for Review of Topical Reports (RAPTR).

RAPTR utilizes the TR review process in LIC-500, “Topical Report Process,” in addition to the LIC-101, “License Amendment Review Procedures,” and LIC-103, “Exemptions from NRC Regulations,” discussed in the TSG for RIPE (Reference 1).

The RAPTR process can be for example incorporated into a new TSG that would be issued by the NRC into a new TSG that uses risk-insights to supplement the TR review process described in LIC-500.

This report contains implementation guidance for the RAPTR process in Appendix A to provide the context on the RAPTR process.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

2 BACKGROUND AND OBJECTIVE

The NRC issued TSG for RIPE (Reference 1), which contains a framework for the streamlined processing of LARs and exemption requests. The objective of RAPTR is to allow issues of minimal safety impact to be addressed generically, and after NRC approval of a TR that contains a generic risk assessment, to be implemented on a plant-specific basis via a LAR, exemption request, or 10CFR50.59 by referencing the NRC approved TR.

Figure 2-1 shows how the RAPTR process will be used with RIPE.

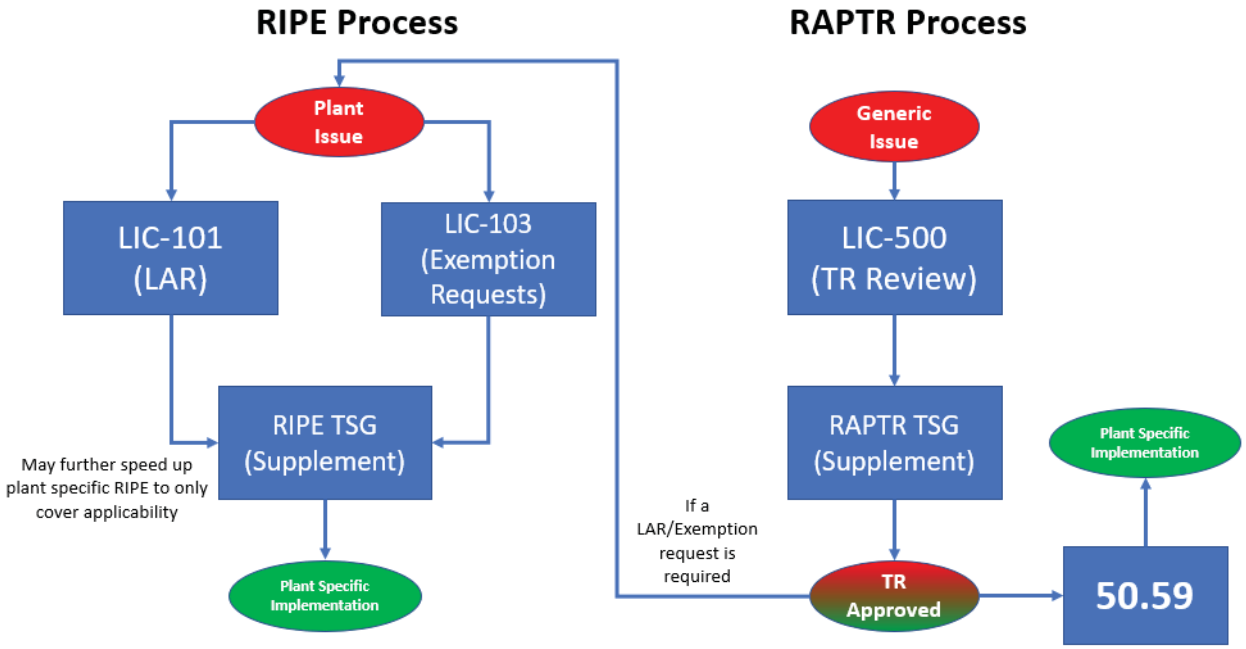

Figure 2-1 RAPTR Process

The RAPTR process starts with a generic issue that can be addressed on a generic basis and can be shown to have minimal safety impacts:

- The “generic risk evaluation,” would be documented in a TR that will be submitted to the NRC for review and approval in accordance with LIC-500, using the new TSG (i.e., the RAPTR TSG).
- A generic risk model will be used for the “risk evaluation” instead of the plant PRA model.
- The TR addresses applicability and limitations of the generic risk study.
- The review of the generic risk assessment that is performed by a plant-specific Integrated Decision Panel (IDP) for RIPE will be performed by a Generic Assessment Expert Team (GAET).
- The NRC approval of the TR via LIC-500 would follow the uncomplicated review process of LIC-500 on the basis that the generic risk assessment satisfies essentially the same requirements described in the RIPE TSG, which are:
    - The issue contributes less than 1×10^{-7}/year to Core Damage Frequency (CDF).

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

- The issue contributes less than 1×10^{-8}/year to Large Early Release Frequency (LERF).
- The issue has no or minimal safety impact in accordance with the "Guidelines for Characterizing the Safety Impact of Issues," (Reference 2).
- The technical adequacy of the risk assessment is confirmed independently from the analysis.
- Note that the cumulative risk criteria is different (see Section 3.2)

The NRC review of a Topical Report that contains a generic risk assessment that demonstrates a minimal safety impact would be classified as “uncomplicated,” allowing a streamlined and accelerated review, i.e., a 6 to 12 month review, that is commensurate with the risk significance of the generic issue being addressed.

After NRC approval of the TR, the NRC review of a plant-specific LAR would be 20 weeks, or 13 weeks for an exemption request that references the NRC approved TR, consistent with the RIPE TSG.

Additionally, a plant-specific implementation that references that NRC approved TR can be implemented via 10CFR50.59, if it is determined that prior NRC approval is not required.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

3 RAPTR PROCESS

RAPTR is a framework that combines elements from the following:

- Elements from RIPE:
  - Definition of generic risk thresholds:
    - RAPTR would characterize a generic issue as a minimal safety impact issue if the risk metric (i.e., CDF, LERF or conservative surrogates thereof) are less than the 1E-7/1E-8 thresholds in the RIPE process. Generic/bounding assessments would be used for the risk assessment rather than plant-specific PRA models. The same guidance for the determination of the safety impact significance that is used for RIPE (Reference 2) would be used for the generic risk assessment.
  - Streamlined NRC review of plant-specific LAR or exemption request submittals (if required):
    - After the TR is approved by the NRC, plant-specific LARs or exemption requests that reference the NRC approved TR would be reviewed consistent with the applicable schedules in the TSG (Reference 1) to allow for an efficient NRC review. The RAPTR process would allow plants to use the plant-specific RIPE process for individual submittals, if required, or to implement a change on a plant-specific bases via 50.59 if it is determined that prior NRC approval is not required.
- Elements from LIC-500 (Reference 3) Expedited NRC review of generic topical reports:
  - A graded approach for the review of a TR as discussed in LIC-500. For an uncomplicated TR, i.e., a RAPTR TR, the review would be completed in 6-12 months.

Because of the generic nature of the issues that will to be addressed within the RAPTR framework, the RAPTR process will be performed in two steps. The first phase is the generic TR review (see Figure 3-1).

Phase 1 – Generic Assessment

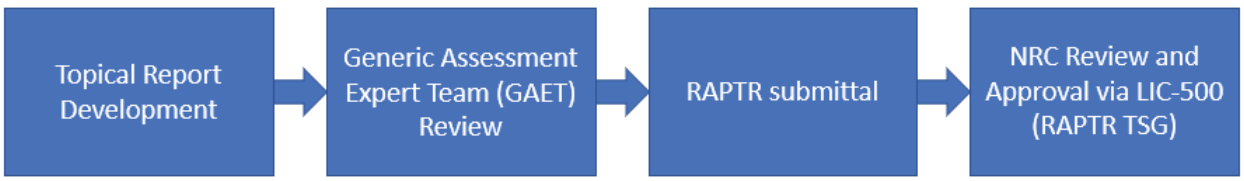

Figure 3-1 RAPTR Phase 1

1. The starting point of the process is the submittal of a RAPTR TR in accordance with LIC-500, which consists of the following elements:

   a. Definition of the issue

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

b. The preliminary, intermediate and final safety assessment documented in the RIPE process (see Reference 2).
c. A quantitative risk assessment supporting the minimal safety impact characterization of the generic the issue in accordance with the RIPE quantitative thresholds.
d. An assessment of all the elements of Risk-Informed Decision Making (RIDM) in accordance with RG 1.174 (Reference 4).
e. Limitations and Conditions of applicability of the generic risk assessment.
f. Documentation of the GAET review and assessment.

2. After NRC concurrence of the final safety assessment that the issue satisfies the quantitative RIPE (i.e., RAPTR) risk thresholds for minimal safety impact, the review would be classified as an Uncomplicated TR review. It is understood that this characterization is normally associated with minor revisions of existing TRs. If the risk assessment of the generic issue satisfies the RIPE risk thresholds based on a preliminary review by the NRC Risk Branch, the review would proceed with a 6-12 month completion and minimal RAIs.

After the RAPTR TR is approved by the NRC, individual plants can implement the TR via a LAR, exemption request, or 10CFR50.59 (see Figure 3-2).

Phase 2 – Plant-Specific Implementation

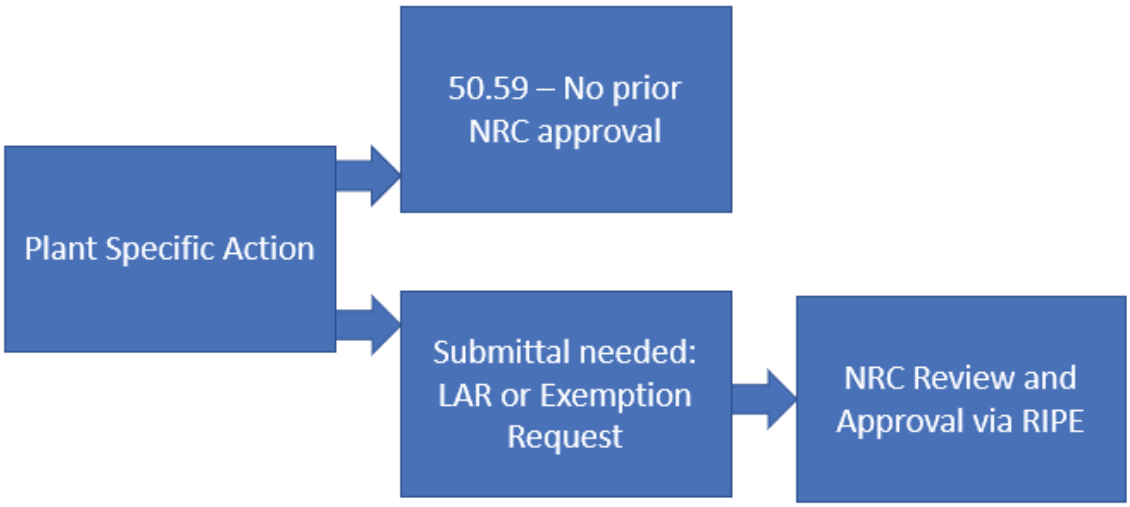

Figure 3-2 RAPTR Phase 2

1. The NRC approved RAPTR TR would be referenced in a 50.59 that is performed for the change under consideration if 50.59 is applicable to the change. If the conclusion of the 50.59 is that prior NRC approval is not required, a plant-specific LAR would not be submitted.

2. Use of the RIPE process to submit a plant-specific LAR or exemption request. Since the generic risk-informed elements of the issue in the RAPTR TR were approved by the NRC in the generic phase (Phase 1), plant-specific LARs or exemption requests should also be reviewed via an expedited NRC review. Thus, the NRC approved RAPTR TR would qualify

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

the plant-specific RIPE submittal as having used a technically adequate risk assessment (i.e., the generic equivalent of a plant-specific PRA that is determined to be applicable to 50.69, TSTF-505 or TSTF-425 applications). The expedited NRC review of plant-specific LAR or exemption request submittals would need to focus on:

a. Applicability of the RAPTR TR to the individual plant submitting a LAR or exemption request.
b. Confirmation that any limitations and conditions in the RAPTR TR are addressed.
c. Plant-specific IDP considerations. The plant IDP would not be typically required to review the plant-specific submittal that references a RAPTR TR because a GAET review has been performed. However, if plant-specific actions are identified by the GAET, or the GAET recommends that a plant-specific IDP should review the submittal, then the IDP review would be included in the submittal and reviewed by the NRC in the plant-specific submittal.

3.1 APPLICABILITY

Consistent with the RIPE process, the RAPTR process may be used for issues that include, but are not limited to:

- 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
- Changes to technical specification (TS)

RAPTR may not be used for the following:

- Any immediate actions necessary for continued safe operation (e.g., to restore compliance with a 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 probabilistically (e.g., fuel changes)
- Any issue associated with changes to emergency planning programs, or changes to security

3.2 RISK METRICS

CDF and LERF are the risk metrics that will be used for RIPE. These same metrics are going to be used for the RAPTR process. In some cases, issues that may be addressed via RAPTR may not be associated with core damage and large early release scenarios. In this case (i.e., for scenarios that do not directly translate into core damage and large early release) the frequency of occurrence will be used. This is acceptable because this surrogate metric is more conservative than an actual CDF/LERF calculation as it assumes a Conditional Core Damage Probability (CCDP) and a conditional Large Early Release Probability (CLERP) of 1.0.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

The same risk thresholds in the plant-specific RIPE process (i.e., 1E-7 CDF and 1E-8 LERF) would also be used for the RAPTR process. For scenarios that do not translate into core damage and large early release scenarios, the same CDF threshold would be used (i.e., the entry condition is less than 1E-7) as a surrogate metric. It is noted that a generic risk analysis that is performed to bound a number of plants is likely more conservative than an individual plant risk estimate, for which all plant-specific conservatism may have been eliminated to reach a specific risk threshold. It can therefore be concluded that a generic bounding risk assessment is more conservative.

Also note that RAPTR is expected to be used for minimal safety impact issues (i.e., less than 1E-7 for CDF and less than 1E-8 for LERF), implying that the added risk to a plant-specific risk profile would not be meaningful when compared with a total risk threshold of 1E-4CDF/1E-5LERF (in other words, a 1E-7 CDF risk increase can be considered to be within the uncertainty band for a total risk on the order of 1E-4 CDF). RAPTR therefore does not address the issue of total plant risk that is included in the plant-specific RIPE.

3.3 TECHNICAL ADEQUACY CONFIRMATION OF THE RISK ASSESSMENT

One of the key elements of the current RIPE process is that multiple previous reviews of the PRA can be leveraged in an expedited NRC review of a subsequent risk-informed evaluation. Since RAPTR is not associated with a plant-specific PRA, the approach discussed below can be used to support and expedited review by the NRC.

A graded risk evaluation approach would be used in the RAPTR process:

1. Simple generic risk assessment.
2. Simple generic risk assessment based on plant-specific PRAs.
3. Complex generic risk assessment.

Depending on the complexity and on the actual basis used for the generic risk assessment, different approaches can be used to confirm the technical adequacy of the risk assessment used for in the RAPTR TR.

1. A simple generic risk assessment would be a straightforward assessment of the frequency (and/or consequences) associated with a specific scenario. A simplified event tree and or fault tree may be used to estimate the frequency of a scenario. In a simple generic risk assessment, all basic data is obtained from well-known and accepted sources of confirmed applicability (e.g., NUREGs, EPRI TRs). In this case, the technical adequacy of the risk assessment is expected to be straightforward, and the GAET would be able to assess it during its review (see Section 3.4).

2. A simple generic risk assessment based on plant-specific PRAs would still use a simplified risk construct to develop frequency estimates, but would also rely on plant-specific information that could be used as bounding estimates. Examples of this approach would be the reliance on CCDP/CLERP information obtained from plant-specific PRAs, or individual probability values (e.g., individual components or system failure probabilities, external hazards estimates, human error probabilities). In this case, the technical

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

adequacy of the risk analysis would be based on the fact that the plant-specific data is obtained from plants with PRAs that would qualify them for the current plant-specific RIPE. Also, in this case, the technical adequacy of the assessment is expected to be relatively straightforward and the GAET would be able to assess it during its review, although it is recommended that a minimum of two GAET members have a background in risk applications.

3. A complex generic risk assessment would be a risk analysis that uses individual elements of the PRA but in a potentially different context (e.g., using a different risk metric or a generic rather than plant-specific analysis). In this case, at least some of the individual elements that are developed in support of the generic risk assessment may also be used in a plant-specific PRA and therefore they can be reviewed through the same peer review process that is used for plant-specific PRAs. The peer review would be conducted with the same process (and guidance) used for the peer review of plant-specific PRAs, that is discussed in NEI 17-07 (Reference 8) and the ASME/ANS PRA Standard (Reference 10) as qualified in RG 1.200 Revision 3 (Reference 9).

   In this more complex case, the risk analysis used in the RAPTR TR would identify the technical elements and associated supporting requirements from the PRA Standard that would be applicable to the analysis performed, and a peer review of the analysis against those supporting requirements would be performed. Since RAPTR would address generic issues in a bounding/conservative way, the review should focus on Capability Category I of the PRA Standard, for those SRs that have capability category differentiation. If the generic risk assessment implements a method that is not used in a plant-specific PRA (or is used in a different context, then a Newly Developed Method (NDM) peer review would also be performed, against the NM technical element of the PRA Standard discussed in RG 1.200, Revision 3 (Reference 9).

   The peer review against the PRA Standard SRs, including the NDM peer review and any Facts & Observations (F&O) closure reviews that are required would be performed prior to the GAET review by a dedicated review team and before the RAPTR TR is submitted.

3.4 GENERIC ASSESSMENT EVALUATION PROCESS

RAPTR uses a GAET to ensure that the appropriate considerations and experiences from the various key disciplines on the team are included in a TR. The NRC has previously incorporated a GAET into RIPE as discussed in (Reference 1), as a means of evaluating issues with generic implications to inform a plant-specific IDP.

The key difference of the GAET in the RAPTR process is that the GAET review will be used in place of the IDP review. However, if plant-specific actions are identified by the GAET, or if the GAET identifies elements that a plant-specific IDP should review before the plant-specific submittal, that information would be included in the submittal and reviewed by the NRC in the plant-specific submittal. For plant issues that do not require a plant-specific submittal and can be implemented via 50.59, the plant-specific IDP recommended by the GAET would become a condition for applicability of the generic evaluation to the individual plant.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

Details on the implementation of a GAET are presented in Appendix A.

3.5 DOCUMENTATION

The structure and content of a RAPTR TR is designed to streamline the review process by the NRC and facilitate Risk-Informed Decision Making (RIDM). As such, the content of the RAPTR TR needs to closely align with the elements of Regulatory Guide (RG) 1.174 (Reference 4).

- Issue Definition:
  - Issue statement:
    This section shall clearly identify the issue that is being proposed to be addressed via RAPTR. The section should clarify whether an exemption request or a LAR is required to be submitted to implement the RAPTR TR or whether it can be implemented via 10 CFR 50.59 without prior NRC approval. Potential alternatives should also be considered, such as the potential for not pursuing the change request due to potential increase in risk resulting from complying with the regulation. The issue statement needs to include a clear indication of the specific regulatory bases that are impacted, along with the existing technical bases.

- Safety Impact:
  - The preliminary, intermediate and final safety impacts assessments discussed in Section 2 of (Reference 2) should be addressed in the RAPTR TR

- Quantitative Risk Assessment:
  - Qualitative and Quantitative elements may be used in the risk assessment in the RAPTR TR:
    - Note that input from multiple plant-specific PRAs may be used for the qualitative elements or to identify trends that will not be used as the rationale for setting specific risk estimates
  - The RAPTR will include a discussion of the source and appropriateness of the data and data sources used
  - If binning of plants is used, binning criteria and the rationale will be justified
  - The generic/bounding quantitative risk assessment may use a conservative CCDP (but not necessarily a 1.0 CCDP), provided that it can be demonstrated to be bounding
  - Assumptions and uncertainties associated with the analysis will be included in the analysis:
    - Ensure uncertainties do not invalidate the bounding nature of the analysis
    - Sensitivities may be needed to address key assumptions

- RG.1.174 elements:
  - All the RIDM elements from RG 1.174 need to be discussed (i.e., regulatory compliance, defense-in-depth, safety margins, quantitative risk criteria and performance monitoring)

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

  - Performance monitoring needs to be discussed; however, it may not be required because of the low-risk significance of the issue

- Applicable limitations and conditions

- GAET review and recommendations

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

4 PHASE 1 – GENERIC REVIEW PROCESS

A RAPTR TR would be reviewed in accordance with LIC-500.

LIC-500 contains four review categories:

- Standard (2+ years)
- Compressed (1 year)
- Uncomplicated (6 months to 1 year)
- SE Confirmation

An uncomplicated review is used when there are minor revisions to an existing TR and the NRC staff has determined based on information at the pre-submittal meeting, that no RAI questions or open items are anticipated. It is recommended that a RAPTR TR that contains a bounding risk estimate that demonstrates minimal safety impact for an issue can be reviewed via an uncomplicated review. The risk analysis is not complex since it is based on bounding and conservative assumptions and methods, the issue is demonstrated to be of low-risk significance and that the (generic) risk analysis tool used is reviewed and approved by the GAET, or a peer review team and the GAET.

The NRC Department of Risk Assessment (DRA) would be the lead technical branch for the review of a RAPTR TR consistent with LIC-500 based on the risk elements discussed in Section 1.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

5 PHASE 2 - INDIVIDUAL PLANT IMPLEMENTATION

The NRC approved RAPTR TR would be referenced in the 50.59 that is performed for the change under consideration. If the conclusion of the 50.59 is that prior NRC approval is not required, a LAR would not be submitted.

If a LAR or exemption request is required to be submitted, the submittal will be made in accordance with the RIPE process and would reference the NRC approved RAPTR TR in the submittal.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

6 REFERENCES

1. United States Nuclear Regulatory Commission Temporary Staff Guidance TSG-DORL-2021-01, Revision 2, Risk-Informed Process for Evaluations, May 2022 (ML22088A136).

2. United States Nuclear Regulatory Commission, Guidelines for Characterizing the Safety Impact of Issues, Revision 2 (ML22088A135).

3. United States Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation. Topical Report Process, LIC-500, Revision 9 (ML20247G279).

4. United States Nuclear Regulatory Commission, Regulatory Guide 1.174, Revision 3, An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis (ML17317A256).

5. NEI 21-01, Revision 0, “Industry Guidance to Support Implementation of NRC’s Risk-Informed Process for Evaluations,” April 2021.

6. EPRI 3002014783, “A Framework for Using Risk Insights in Integrated Risk-Informed Decision-Making,” February 2019.

7. NEI 16-09, Revision 1, “Risk-Informed Engineering Programs (10 CFR 50.69) Implementation Guidance,” August 2020.

8. NEI 17-07, Revision 2, Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard, August 2019 (ML19228A242).

9. United States Nuclear Regulatory Commission, Regulatory Guidance 1.200, Revision 3, Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities, December 2020 (ML20238B871).

10. ASME/ANS RA-Sa-2009, Addenda to ASME/ANS RA-S-2008, Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

APPENDIX A – SUPPORTING INFORMATION AND IMPLEMENTATION GUIDANCE

This appendix provides supporting information and implementation guidance that would not be included in a TSG. This information is provided for context and could be added in an industry document (e.g., an NEI or PWROG document).

A.1 GAET IMPLEMENTATION DETAILS

The GAET process discussed in this section is based on NEI 21-01 (Reference 5), includes elements from the plant-specific IDP process and the five principles of Risk Informed Decision Making (RIDM) in RG 1.174 (Reference 4) and EPRI 3002014783 (Reference 6), to ensure an adequate review is performed to support the RAPTR process.

A.1.1 Purpose of the GAET

The purpose of the GAET is to review a RAPTR TR. The GAET reviews the characterization of the importance of the regulatory issue from a generic standpoint, as well as the overall assessment and safety impact. The composition of the GAET would consist of a panel of industry participants and experts that fulfill many of the same functions as a plant-specific IDP.

The GAET is responsible for ensuring the issue is fully defined and all the potential safety impacts have been identified. If the GAET identifies that it needs additional information in order to make a final recommendation regarding the safety impact, additional experts will be consulted and included in the GAET. The goal of this phase of the review is to identify and review all the available information regarding the issue and characterize its safety impact.

A.1.2 GAET Composition

The review of the generic evaluation may be performed by an industry expert team in combination with an NRC expert team, or individually by the industry or NRC. Each GAET should have a GAET Coordinator identified. The GAET Coordinator will be responsible for coordinating and conducting the GAET meetings and preparing the required documentation.

The GAET process does not require a 10CFR50 Appendix B program for the review. However, the process includes the principal elements of an effective 10CFR50 Appendix B quality assurance review of documents via:

- Use of qualified reviewers
- Use of reviewers who are independent of the TR being reviewed
- Preparation of a list of comments to be addressed
- Documentation of the conclusions of the review

The GAET is comprised of industry or NRC experts with relevant expertise about the issue being evaluated. The GAET composition will vary depending upon the issue. Generally, the GAET is

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

composed of knowledgeable personnel whose expertise represents the important process and functional elements of the industry and regulatory processes, such as operations, engineering, nuclear risk management, industry operating experience, and licensing. The GAET members will have an essential understanding of the issue's safety impact, as well as familiarity with the RAPTR process and approach. The team will call upon additional personnel, SMEs, or external consultants, as necessary, to assist in the review. Experience, plant knowledge, familiarity with current regulatory issues, and independence, are important elements in the selection of GAET members.

Note that this process endorses a reasonable and practicable interpretation of GAET member independence. With the exception of individuals who have worked on the subject RAPTR TR, there are no exclusion criteria for the composition. A requirement of absolute independence coupled with the need for adequate technical expertise can be difficult to achieve in some situations. Reviewers who may have some role in the development of the RAPTR TR or sections of the TR can be part of the GAET (consistent with a plant-specific IDP), and their input to the TR and participation to the GAET should be documented in the GAET final documentation.

In general, there should be at least five experts designated as members of the GAET with expertise in the following fields, as required based on the issue to be reviewed:

- Plant operations
- Design and systems engineering
- Safety analysis
- PRA and RIDM
- Licensing
- Other Subject Matter Experts as needed

GAET members should have at least 5 years of experience in the field they are representing, be knowledgeable in the area associated with the specific issue being reviewed and be familiar with defense-in-depth fundamentals as well as the GAET and RAPTR process. Representatives from plant operations should be a current or former Senior Reactor Operator (SRO) from a nuclear power plant to which the TR is applicable to.

A.1.3 GAET Process

The following process is applicable to industry led GAET reviews.

A.1.3.1 GAET Process

The first activity is to identify the specific areas of expertise required for the GAET and to identify the GAET Coordinator.

Once the specific areas of expertise are identified, the GAET Coordinator and the preparer of the RAPTR TR, are responsible for identifying and assigning the remainder of the team. Each team member will be responsible for providing a summary of their qualification as it pertains to the specific RAPTR TR to be reviewed.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

A.1.3.2 Pre-Review Activities

Consistent with the IDP implementation guidance in NEI 16-09 (Reference 7), it should be noted that training of the GAET is extremely important to ensure the process is implemented correctly and efficiently. Once the team has been assembled and the team understands the scope of the review, the GAET Coordinator will be responsible for training the team on the GAET process to ensure that all team members understand the following attributes at a minimum:

- GAET process
- RAPTR process
- PRA Fundamentals:
  - The relationship between frequency and consequence (i.e., risk)
  - Interpretation of risk-importance measures
  - The role of sensitivity studies and change-in-risk evaluations
- Defense-in-depth philosophy and requirements to maintain this philosophy
- RIDM process
- Roles and responsibilities
- Scope of the review
- Regulatory application

In addition to providing the training to the team, the GAET Coordinator will be responsible for interfacing with the preparer of the RAPTR TR as well as with the GAET team to establish minimum duration of the review. Note that the RAPTR TR must be finalized prior the the start of the GAET review (i.e., a GAET should not review draft TRs).

A.1.3.3 GAET Review

The GAET must review the TR against each of the five principles of RIDM from RG 1.174 (Reference 4) from the perspective of each individual discipline represented, as well as from an integrated perspective, to ensure that a RAPTR TR meets this set of key principles. In addition, the GAET will review the final safety impact assessment and formulate the final GAET recommendation for the TR. In addition to the GAET comments and recommendations on the TR, any plant-specific considerations or characteristics beyond those contained in the TR that should be reviewed by a plant-specific IDP when applying the generic TR to an individual plant should be identified. However, it should be noted that implementation of a TR is ultimately the responsibility of each applicable licensee.

To kick off the GAET review, the preparer of the TR will give a presentation that covers the scope and technical bases provided in the TR and respond to questions from the GAET. The preparer of the TR must also provide the GAET with a package of relevant information in advance of the review to allow an adequate review by the team.

The review can be started once the GAET members receive the TR and any supporting documentation. The GAET must use a consensus process (majority agreement with a decision)

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

for the evaluation. This process must allow for the resolution or documentation of differing professional opinions.

At the conclusion of the GAET review period, the GAET Coordinator will conduct a meeting to, review the roles and responsibilities of the meeting, as well as the conclusions from each portion of the review as follows:

- RIDM principles
- Final safety impact assessment
- Specific GAET comments and responses

In addition to the specific GAET comments, the GAET recommendation for the TR will also be presented. GAET recommendations may include:

- Recommendation to proceed with submitting and requesting NRC approval of the TR per the RAPTR process:
    - No GAET comments on the TR
- Conditional recommendation to proceed with submitting and requesting NRC approval of the TR via the RAPTR process:
    - Minor GAET comments on the TR should be resolved or dispositioned prior to submittal of the TR to the NRC, however, no follow up GAET review is necessary
- Recommendation to not submit and request NRC approval of the TR:
    - GAET identification of significant deficiencies in the TR
    - The TR must be revised to resolve the significant deficiencies identified by the GAET
    - The revised TR would be resubmitted to the GAET for an additional review

The GAET must recommend that the revised TR is acceptable in order for it to be submitted to the NRC for review and approval via the RAPTR process.

A.1.3.4 GAET Documentation

The GAET Coordinator is responsible for providing a summary report of the GAET review. This report should include the following:

- Definition of the scope of the review
- Summary of the team overview and qualifications:
    - Resumes and statement of independence for each review team member
    - GAET member signatures
- Summary of the GAET review process
- Details of all GAET comments (if applicable)
- GAET recommendation on how to proceed with submitting and requesting NRC approval of the TR via the RAPTR process

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

- Dissenting opinions (if applicable)
- Plant-specific limitations, considerations or characteristics

The GAET report will be included in the RAPTR TR that would be submitted to the NRC for review and approval.

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)

This page was added to the quality record by the PRIME system upon its validation and shall not be considered in the page numbering of this document.

Approval Information

Author Approval Maioli Andrea Oct-26-2022 13:16:59
Author Approval Labarge Nathan R Oct-26-2022 13:17:38
Author Approval Meneely Jennifer E Oct-26-2022 14:07:19
Reviewer Approval Andrachek James Oct-26-2022 16:43:36
Manager Approval Charleroy Amanda L Oct-26-2022 21:43:45
Manager Approval Mirizio Damian S Oct-27-2022 08:12:46

Files approved on Oct-27-2022

*** This record was final approved on 10/27/2022, 8:12:46 AM. (This statement was added by the PRIME system upon its validation)