OFFICE OF NUCLEAR REACTOR REGULATION

LIC-504, Revision 5	Integrated Risk-Informed Decisionmaking Process for Emergent Issues
Volume 500	Regulatory Improvements
Approved By: Date Approved: Effective Date: Certification Date:	Andrea D. Veil March 4, 2020 March 9, 2020 March 9, 2025
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Summary: Revision 5 of LIC-504, "Integrated Risk-Informed Decisionmaking Process for Emergent Issues," incorporates lessons learned since the issuance of Revision 4 in 2014. Major changes include (1) establishing mechanisms to adjust the resources necessary to evaluate and document issues based on their complexity and safety significance, (2) adding consideration to avert unnecessary radiation exposure to workers as a subsidiary criterion in risk-informed decisionmaking in accordance with 10 CFR Part 20, "Standards for Protection Against Radiation," (3) establishing performance measures for deliverables associated with LIC-504, (4) facilitating the use of LIC-504 when other processes exist to address issues to reflect recent staff practice, (5) harmonizing with other guidance the threshold for characterizing issues as "very low risk significance" for change in core damage frequency from $1x10^{-7}$/year to $1x10^{-6}$/year, (6) incorporating current practices on treatment of safety margins, (7) providing guidance on decisionmaking error traps, (8) further clarifying NRR versus regional roles with respect to assessing generic implications of emerging issues, and (9) providing guidance on regulatory options that should be considered based on safety significance, similar to the concept in Management Directive 8.3, "NRC Incident Investigation Program," which uses safety significance to narrow the options for regulatory response.	
Training:	Self-study
ADAMS Accession Number:	ML19253D401

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ADAMS Accession No.: ML19253D401 Pkg: *via email NRR-071

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NAME	ASchwab	SWeerakkody	JMarshall	BWittick	JMonninger	CMiller	LLund	CErlanger
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1. POLICY

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to employ the strategies in NUREG-1614, Volume 7, "Strategic Plan: Fiscal Years 2018–2022," issued February 2012 (Ref. 1), to meet the agency's performance goals. In particular, the U.S. Nuclear Regulatory Commission (NRC) will use sound science and state-of-the-art methods to establish, where appropriate, risk-informed and performance-based regulations and use domestic and international operating experience to inform decisionmaking.

In 1995, the NRC published in the *Federal Register* (60 FR 42622) its probabilistic risk assessment (PRA) policy (Ref. 2), which states that an overall policy on the use of PRA methods in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner. In that policy document, the Commission stated that it believes the use of PRA technology in NRC regulatory activities should be increased to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach.

In its staff requirements memorandum (SRM) to SECY-98-144, "Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999 (Ref. 3), the Commission stated the following:

> A "risk informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A "risk-informed approach" enhances the deterministic approach by: (a) allowing explicit consideration of a broader set of potential challenges to safety, (b) providing a logical means of prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (c) facilitating consideration of a broader set of resources to defend against those challenges, (d) explicitly identifying and quantifying sources of uncertainty in the analysis (although such analyses do not necessarily reflect all important sources of uncertainty), and (e) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions.

On May 11, 2017, nuclear industry representatives and the NRC staff briefed the Commission on risk-informed regulatory activities. The briefing included a status of the NRC's and industry's risk-informed initiatives and an overview of successes and areas of focus for advancing risk-informed regulation. On June 26, 2017, the Commission issued SRM-M170511, "Staff Requirements—Briefing on Risk-Informed Regulation" (Ref. 4) and directed the staff to provide it with an information paper discussing its plans for increasing staff capabilities to use risk information in decisionmaking activities. The staff responded to SRM-M170511 in SECY-17-0112, "Plans for Increasing Staff Capabilities to Use Risk Information in Decision-Making Activities," dated November 13, 2017 (Ref. 5). SECY-17-0112 included the staff's proposal for increasing its capability to use risk information in decisionmaking and describes challenges toward further progress in risk-informed decisionmaking (RIDM) and measures that the staff is taking to overcome these challenges. The staff developed and implemented the RIDM document, "Action

Plan, Risk-Informed Decision-Making Operating Reactor Business Line," dated November 27, 2018 (Ref. 6).

2. OBJECTIVES and SCOPE

The objective of this office instruction is to present risk-informed options to disposition emergent safety issues and document the bases of those decisions.

Safety issues emerge as a result of U.S. or international operating experiences. Sometimes, they emerge as a result of regional inspections. When issues are the result of inspections, they may identify the potential for plant-specific and generic implications. The NRC regions are equipped with processes (Ref. 7) and expertise to resolve plant-specific issues in a risk-informed manner. Therefore, LIC-504 analyses are not necessary to resolve plant-specific issues unless a region believes that an issue may require issuance of an order or have potential generic implications. In such cases, after performing a bounding risk analysis, regions may ask NRR to perform an LIC-504 analysis.

It is important to note that this procedure simply provides an optional input to LIC-106, "Issuance of Safety Orders," dated December 17, 2003 (Ref. 8). LIC-106 is the higher tier procedure that the NRR staff must follow to issue safety orders. Management Directive (MD) 9.27, "Organization and Functions, Office of Nuclear Reactor Regulation," dated January 24, 2017 (Ref. 9), is the NRC procedure that specifies the NRR role with respect to issuing orders.

The NRC originally created this process for RIDM on emergent issues relevant to nuclear power plants for which there are no other existing processes. However, it has used it to assist in making risk-informed decisions by providing a process to document the bases and considerations for those decisions, even when other processes (such as technical specifications, generic communications, regulatory compliance, and inspections and enforcement) existed to address the emerging issue. In such cases, the staff used LIC-504 to risk-inform available regulatory responses (e.g., issuing information notices as opposed to bulletins, following up with prompt or delayed inspections at potentially vulnerable facilities). LIC-504 has not been used to obviate the need to follow existing higher tier processes.

Because the procedure is focused on emergent safety issues, its applicability is limited to operating plants. Therefore, issues related to the design of new light-water reactors and advanced reactors are outside the scope of this procedure. LIC-504 guidance in Appendices B, C, and D may be used for research reactors as appropriate.

As the LIC-504 team embarks on the analyses, it is also important to note that LIC-504 is a two-step process that could result in four different scenarios:

(1) determining whether to take immediate regulatory action, such as issuing an order to shut down the unit/s at the site where the concern was identified

(2) determining whether immediate regulatory action, such as issuing orders to shut down other sites, is necessary (i.e., generic concern)

(3) developing risk-informed options to resolve the issue at the unit or site of concern

(4) developing risk-informed options to resolve the issue at other potentially affected units

3. BACKGROUND

In GAO-04-415, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," dated May 5, 2004 (Ref. 10), the U.S. General Accounting Office (GAO) (now the U.S. Government Accountability Office) made several recommendations for addressing problems that contributed to the Davis-Besse vessel head degradation that could occur at nuclear power plants in the future. In the areas of risk evaluation, communication, and the decisionmaking process for determining if plant shutdown is warranted, the GAO made two recommendations:

(1) Develop specific guidance and a well-defined process for deciding when to shut down a nuclear power plant. The guidance should clearly set out the process to be used, the safety-related factors to be considered, the weight that should be assigned to each factor, and the standards for judging the quality of the evidence considered.

(2) Improve the NRC's use of PRA estimates in decisionmaking by ensuring that the risk estimates, uncertainties, and assumptions made in developing the estimates are fully defined, documented, and communicated to NRC decisionmakers and provide guidance to decisionmakers on how to consider the relative importance, validity, and reliability of quantitative risk estimates in conjunction with other qualitative safety-related factors.

This office instruction and LIC-106 address these recommendations. The staff recognizes that the various inputs to a given decision can be very different, thus making it difficult to develop a formal process for combining them. Therefore, the LIC-504 process focuses on documenting those inputs so that the decisionmaker can clearly understand their contribution to the resulting decision. LIC-504 also focuses on documenting the decision so that the key assumptions are identified and suitably qualified to address uncertainties.

4. IMPORTANT NOTES AND CAUTIONS

- **Immediate Plant Shutdown:** If at any time it is determined that an immediate shutdown of a plant is required, LIC-106 or the process in the NRC Enforcement Manual (Ref. 11) should be implemented. If LIC-504 is already in process when it is determined that an immediate plant shutdown is necessary, LIC-504 should not be permitted to interfere with necessary and timely action. Cognizant management may suspend or curtail LIC-504 at that time.

- **Plant Restart:** NRC Inspection Manual Chapter 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns," dated March 1, 2018 (Ref. 12), provides a framework for the oversight of licensee operations and performance, NRC inspections, and restart efforts for plants shut down with significant performance or operational concerns. In some circumstances, LIC-504 may be used to provide insights into that process. For example, in 2013, an LIC-504 analysis determined whether

there was an immediate safety concern with restarting Fort Calhoun pending completion of these further analyses (Ref. 13).

- **Communicating Risk and Engineering Insights, Uncertainties, and Key Assumptions:** SRM-SECY-98-144 provides a Commission-endorsed definition and interpretation of RIDM. In RIDM, the NRC staff uses the best available probabilistic and deterministic information. Usually, models estimate effects such as risk, thermal hydraulics, or materials degradation. Therefore, both LIC-504 team members and decisionmakers must be cognizant of the factors that contribute to uncertainty in predictive models (both probabilistic and deterministic), and the need to identify, characterize, and communicate the uncertainties to decisionmakers. NRC Training Course P-109, "Assessing the Adequacy of Models for Risk-Informed Decisions," issued March 2019 (Ref. 14), a 1-day course aimed at improving awareness of this topic, discusses the fact that all models are just estimates of reality and subject to many implicit assumptions and biases. Much time is spent in the class on developing an appreciation for the value of a questioning attitude toward model use and reliance. The analyst is responsible for explicitly understanding and communicating to decisionmakers those assumptions, the limits of model applicability, and the uncertainty on the output. Decisionmakers should be mindful of key assumptions, including uncertainties in probabilistic and deterministic models and hidden decision error traps.

- **Participative Decisionmaking and Hidden Decisionmaking Error Traps:** With respect to the NRC's participative decisionmaking, decisionmaker(s) should consider, in a timely manner, as many viewpoints as practical and critically assess the merits of each viewpoint to make the most informed and sound decision. Implementing this leadership expectation gives an opportunity for all involved in a specific LIC-504 case to exercise open and constructive dialogue for safety-focused outcomes. In the decisionmaking process, leaders may also need to be aware of hidden decisionmaking error traps, such as the following:

  Anchoring: giving disproportionate weight to the first information you receive

  Status quo: favoring alternatives that perpetuate the existing situation

  Sunk costs: making choices in a way that justifies past, flawed choices

  Confirming evidence: seeking information that supports your existing point of view

  Estimating and forecasting: being overly influenced by vivid memories when estimating

  The reference material for NRC course P-109 and a *Harvard Business Journal* article entitled, "The Hidden Traps in Decision Making," issued September/October 1998 (Ref. 15), include additional reading and suggested approaches to minimizing error traps.

- **Using Documentation Templates**: This procedure provides templates and worksheets as guidance for documenting the evaluation of any options

developed to address the issue. Use of these worksheets is optional. Every item listed for possible consideration need not be addressed; rather, the worksheets or templates are intended to encourage a structured thought process, only a portion of which may apply to a given issue or option. When documenting an analysis, the user may address only the items that apply to an option or issue or the items that will help to differentiate among the various options.

- **Minimizing Process Conflicts**: When an emergent issue is identified, multiple processes may be implemented simultaneously. For example, processes such as event response and inspection may be in progress and occur simultaneously with the LIC-504 effort. Under such circumstances, as shown in Figure 2, the LIC-504 team (comprising, at a minimum, a subject matter expert on the emerging issue and a qualified risk analyst) must develop strategies to prevent conflicts between the process owners (e.g., if the emerging issue pertains to a technical specification, the process owner is the Branch Chief responsible for technical specifications or his or her assignee) who address the issue and the LIC-504 team. This can be accomplished by an LIC-504 team meeting, the LIC-504 process owner (PRA senior level advisor in the Division of Risk Assessment (DRA)), lead licensing project manager (PM) for the site in question, and the owner of the existing process to which the issue belongs. In most cases, an integrated review team is well-suited for coordinating, planning and tracking resources, and scaling the LIC-504 review to the need.

- **Determining Lead Responsibilities**: Establishing and agreeing on the lead responsibilities to resolve a plant-specific or a generic concern will minimize potential miscommunications and misunderstandings within the NRC staff that may occur during an LIC-504 analysis. Of concern are compliance and operability issues that have generic implications. In general, NRR is typically best suited to take the lead in resolving the generic implications of the issue across all affected stakeholders using whatever existing process is designed to resolve the generic implication in question. For issues identified through the inspection process that involve both NRR and the region, the region should typically take the lead on plant-specific issues and NRR should take the lead on generic issues. Under these circumstances, LIC-504 may be used to risk-inform the options within the construct of the higher tier process or regulatory requirements as opposed to obviate the need to follow them.

- **Resolving Plant-Specific vs Generic Issues Using LIC-504:** NRC's MD 9.27 articulates the role of NRR and the regions on issuing orders; in summary, giving the NRR Office Director the authority to issue orders. NRR will assume the lead to perform LIC-504 analyses for both plant-specific and generic issues. However, regulatory decisions as they pertain to the plant-specific versus generic issues could be different, in part because the staff may have significantly more information (less uncertainties) relating to the plant-specific issue as a result of inspections. Once the team recommends its risk-informed decision with respect to the plant-specific issue, the LIC-504 process for the plant-specific issue may be exited while continuing the LIC-504 analysis for the generic issue.

4.1 Risk-Informed Approach to Decisionmaking

As defined in SRM-SECY-98-144, a "risk-informed" approach to regulatory decisionmaking represents a philosophy whereby risk insights are considered with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. In Regulatory Guide (RG) 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," issued January 2018 (Ref. 16), five key principles of risk-informed regulation serve as the foundation of sound, risk-informed decisionmaking:

(1) meeting current regulations
(2) maintaining sufficient defense in depth
(3) maintaining sufficient safety margins
(4) ensuring that increases in risk are small
(5) ensuring that there are performance measurement strategies to monitor change

Various risk-informed processes generally differ in how they demonstrate that the key principles are satisfied. The following paragraphs compare the use of these key principles for LIC-504 with their use in reviewing acceptability of changes to license amendment requests.

It should be noted that integrated RIDM is inclusive of other considerations when using the five key principles stated above. Based on the issue, the NRC staff may consider other factors that are within the scope of the NRC (e.g., risk tradeoffs, averted radiation exposure to plant workers, Enterprise Risk Management (ERM) considerations[1]) to evaluate merits of various options.

Meets current regulations (unless an exemption is sought): NRC regulations may not fully address the potential issues revealed when new information comes to light. In some cases, the new information may reveal that a licensee **is not** in compliance with a regulation. A risk-informed decision may involve choosing among options that involve how long a situation may exist before action must be taken to achieve full regulatory compliance. In other cases, the new information may not clearly show that a licensee or a group of licensees is not in compliance but may show that the **potential** for noncompliance exists. In such cases, risk-informed bases generated under LIC-504 may be used to evaluate the rigor or timeliness of options that must be considered to resolve such issues using applicable processes in accordance with NRC guidance provided in the Enforcement Manual or guidance in Inspection Manual Chapter 410, "Notices for Enforcement Discretion," dated March 13, 2013 (Ref. 18).

To issue the operating license, the NRC found there is reasonable assurance that (1) the activities authorized by the operating license can be conducted without endangering

[1] In Office of Management and Budget (OMB) Circular A-123, "Management's Responsibility for Enterprise Risk Management and Internal Control," dated July 15, 2016 (Ref. 17), risk management is a series of coordinated activities to direct and control challenges or threats to achieving an organization's goals and objectives. ERM is an effective agencywide approach to addressing the full spectrum of the organization's external and internal risks by understanding the combined impact of risks as an interrelated portfolio, rather than addressing risks only within silos. ERM gives an enterprisewide, strategically aligned portfolio view of organizational challenges that provides better insight about how to most effectively prioritize resource allocations to ensure successful mission delivery.

public health and safety, and (2) such activities will be conducted in compliance with the Commission's regulations. Therefore, compliance with regulations affords a presumption of adequate protection of public health and safety. New information about an unforeseen or substantially more likely hazard could raise "special circumstances" that might rebut this assumption. In NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 19.2, "Review of Risk Information Used To Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," issued June 2007 (Ref. 19), Appendix D includes additional information on "special circumstances" that could introduce significant and unanticipated risks. In such cases, the NRC staff would assume the burden to prove that the existing staff positions or regulatory requirements do not support the presumption of adequate protection. To that end, Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting," provides regulatory requirements on backfitting. SRM-SECY-18-0049, "Staff Requirements—SECY-18-0049—Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality, and Information Collection,'" dated May 29, 2019 (Ref. 20), contains recent Commission guidance on backfitting and forward fitting.

In evaluating compliance with existing regulations, the LIC-504 team should also consider the recent Commission position documented in SRM-SECY-19-0036, "Application of the Single Failure Criterion to NUSCALE Power LLC's Inadvertent Actuation Block Valve," dated July 2, 2019 (Ref. 21). That SRM states that, in any licensing review or other regulatory decision, the staff should apply risk-informed principles when strict, prescriptive application of deterministic criteria such as the single failure criterion is unnecessary to provide for reasonable assurance of adequate protection of public health and safety.

Consistent with the defense-in-depth philosophy: RG 1.174 starts with the presumption that defense in depth is adequate for the existing plant and evaluates the requested change to determine whether defense in depth is maintained. For emergent issues, this key principle is used to compare various options proposed for addressing the issue. Defense in depth may be at the heart of some issues—that is, the new information may reveal insufficient defense in depth for the existing facility. Note that discussions of defense-in-depth principles in RG 1.174 focus on reviews of license amendment requests. Appendix E to this office instruction provides additional guidance to assist in determining the extent to which the various options being considered maintain defense in depth, including guidance on how defense in depth must be interpreted for an LIC-504 analysis versus licensing amendment reviews.

Maintain sufficient safety margins: RG 1.174 includes meeting codes and standards or their alternatives and the safety analysis acceptance criteria in a plant's licensing basis (e.g., updated final safety analysis report and supporting analysis). The LIC-504 approach to this key principle is somewhat different in that the degraded safety margin of the affected component or function should be viewed within the context of the existing facility and its overall risk profile. For example, substantive loss of safety margin of a single component or system may not necessarily substantially erode the overall safety margin of the facility because of redundancies and diversities, or it could represent a loss of function or introduce a potential common-cause failure. Another notable difference between how safety margins must be considered for LIC-504 in comparison to RG 1.174 is the need to consider the threshold at which failure may occur as opposed to simply considering the safety limit

or limits associated with codes and standards. Note that discussions of safety margins in RG 1.174 focus on reviews of license amendment requests. Appendix E to this office instruction provides additional guidance to assist in evaluating how well each proposed option addresses an emergent issue.

Increases in risk should be small: RG 1.174 concentrates on the change in risk associated with the proposed amendment to a plant's licensing basis. For emergent issues, the total risk associated with the new or increased hazard may provide a basis for concluding that an immediate safety concern exists, such that the NRC must act promptly to put a nuclear power plant in a safe condition. The risk associated with each proposed option for resolving the issue, in conjunction with the other key principles, may help the decision authority choose from among the options. Note that a quantitative risk assessment may prove difficult to obtain for some emergent issues. Qualitative risk assessments may be used as appropriate.

Use performance measurement strategies to monitor change: In RG 1.174, the licensee should install monitoring to ensure that no unexpected adverse safety degradation occurs because of the change(s) and to prevent the aggregate impact of changes that affect a large class of structures, systems, and components (SSCs) from leading to an unacceptable increase in the number of failures, including possible common-cause mechanisms. Similar to that, when LIC-504 evaluates options to resolve an emerging issue, the team should be mindful of the need for performance monitoring on the part of the licensee. It is noted here that licensees (as opposed to the NRC staff) are required to monitor the effectiveness of maintenance at nuclear power plants (Ref. 22). Uncertainties associated with the assessment of risk, defense in depth, and safety margin could significantly impact the characteristics of performance measurement strategies required to address the emerging issue. Appendix E includes additional guidance on performance monitoring and compensatory measures.

Treatment of Uncertainty: Treatment of uncertainty is a significant component in integrated RIDM. Generally speaking, there are two main types of uncertainty: aleatory and epistemic. Aleatory uncertainty is based on the randomness of the nature of the events or phenomena and cannot be reduced by increasing the analyst's knowledge of the systems being modeled. Therefore, it is also known as random uncertainty or stochastic uncertainty. Epistemic uncertainty is the uncertainty related to the lack of knowledge about or confidence in the system or model and is also known as state-of-knowledge uncertainty. PRA models explicitly address aleatory uncertainty, which results from the randomness associated with the events in the model logic structure. The random occurrence of different initiating events with subsequent failure of components to operate and human errors lead to a large number of possible accident sequences that are accounted for in the event and fault trees used in a PRA model.

Figure 1, an excerpt from Revision 1 of NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," issued March 2009 (Ref. 23), shows how integrated decisionmaking treats uncertainties, together with various elements of risk-informed principles to generate sound regulatory decisions. This figure provides high-level guidance on how some components of epistemic uncertainties (e.g., parametric) can be treated under the LIC-504 process. The key salient point of Figure 1 is the correlation between step 4 (Define Implementation and Monitoring Program) and "Assessing Uncertainties." Irrespective of the approach used in LIC-504 analyses, the team should carefully consider key

assumptions and uncertainties and use those to devise appropriate implementation and monitoring strategies.

Often, since LIC-504 analyzes emerging issues for which the information on the magnitude of the degradation is limited, significant uncertainties may be associated with the estimated failure probabilities of potentially affected SSCs due to the emerging issue. In such cases, sensitivity analyses and bounding risk analyses can be used to select and implement appropriate performance measurement strategies.

The LIC-504 team should also carefully consider matters concerning “completeness uncertainty,” in that the PRA model may not implicitly or explicitly model the SSCs affected by the emerging issue adequately. Generally, these situations can be addressed by careful mapping of the affected SSCs (to a parameter explicitly modelled in PRA). The LIC-504 team should secure PRA expertise to accurately address such situations.

Treatment of Key Assumptions:

RG 1.1200, Revision 2, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” issued March 2009 (Ref. 24), states that a key assumption is one that is made in response to a key source of model uncertainty in the knowledge that a different reasonable alternative assumption would produce different results, or an assumption that results in an approximation made for modeling convenience in the knowledge that a more detailed model would produce different results. A reasonable alternative assumption is one that has broad acceptance within the technical community and for which the technical basis is at least as sound as the assumption being made. In making a regulatory decision, risk insights are integrated with considerations of defense in depth, safety margins, and performance monitoring to address the potential impact of key assumptions.

Section 4.2 describes the entry and exit conditions for LIC-504, including guidance on selecting the simplified, standard, or detailed approach. Section 4.3 is an overview of the RIDM process, which is applicable to any of the approaches. Appendix B provides guidance on the simplified approach; Appendix C, on the standard approach; and Appendix D on the detailed approach to RIDM.

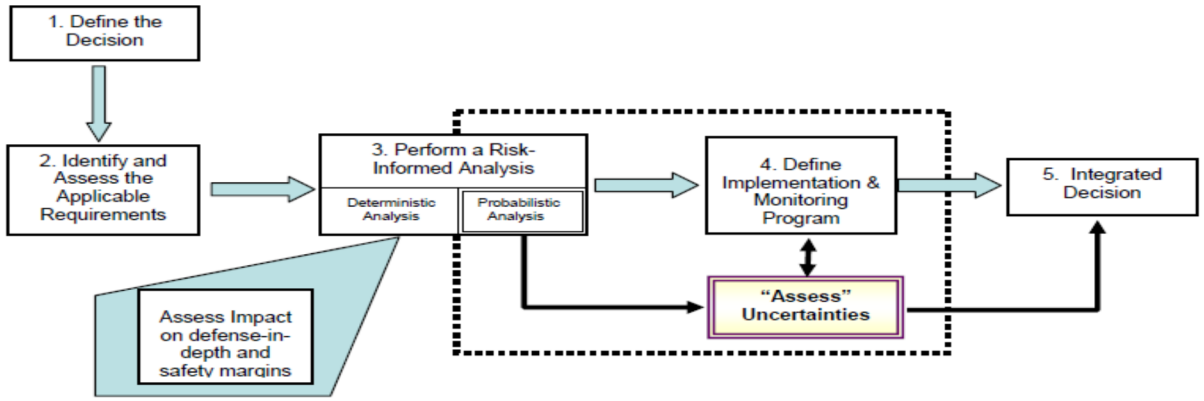

Figure 1 Elements of integrated risk-informed decisionmaking process

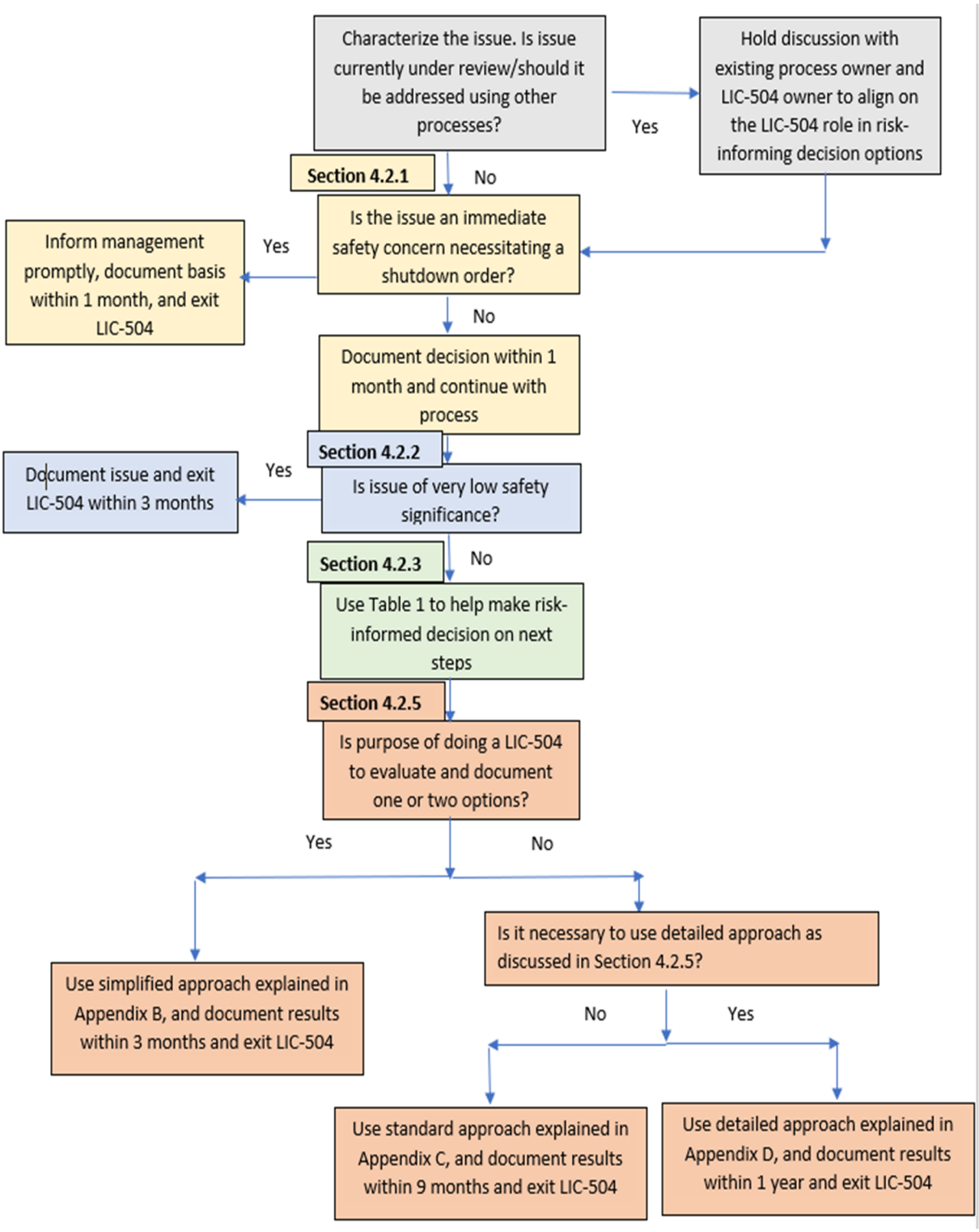

Figure 2 LIC-504 process

4.2 Entering and Exiting LIC-504

Figure 2 shows the steps to enter and then exit LIC-504, the first step of which is to characterize the issue.

LIC-504 is generally used when (1) new information reveals an unforeseen hazard or a greater potential for a known hazard to occur, such as identification of an issue that may increase risk, or (2) no other NRC process exists for addressing the issue. The NRC staff can also use LIC-504 to risk-inform options available to resolve issues within the construct of other existing processes. In some situations, if there are uncertainties about the process that must be used to address an issue, the results of LIC-504 can assist in selecting the appropriate process for resolving the issue.

LIC-504 should be exited when a risk-informed decision has been made and the bases for the decision have been documented (i.e., resolution of the issue using LIC-504 input is likely to continue after LIC-504 is exited). In some situations, LIC-504 for a plant-specific issue may be exited while the LIC-504 for the associated generic issue continues.

4.2.1 Is Immediate Regulatory Action Required?

The first GAO recommendation involved guidance for when to shut down a nuclear power plant. Therefore, if at any stage of the evaluation, it is determined that regulatory action is needed to place or maintain a plant in a safe condition, LIC-106 or the NRC Enforcement Manual process should be entered. Whether an issue warrants immediate regulatory action may be determined separately from LIC-504 if a different process determines that an issue constitutes an immediate public health and safety concern.

Interaction with the appropriate NRC regions will follow established protocol. Use of LIC-504 should not be permitted to interfere with taking necessary and timely action and may be suspended or curtailed by division management.

The following guidelines may be used by the LIC-504 team to question whether additional regulatory action is required to place or maintain the plant in a safe condition:

a. Defense in depth of the facility is significantly degraded (e.g., multiple barriers are moderately to significantly degraded, functional redundancy or diversity is significantly compromised, or vulnerability to single failures is significantly increased) (see Appendix E for additional guidance).

b. Significant loss of safety margin contributes to a facilitywide safety impact (e.g., cliff edge effects) (see Appendix E for additional guidance).

c. Impact is noticeable on public confidence in the U.S. nuclear enterprise as a safe and viable energy source.

d. Potential impact is felt on the regulator’s reputation as a safety regulator.

e. Potential radiation exposures may be incurred by a licensee to implement the option.

f. The risk impact from internal or external events is high, as determined by using risk metrics such as the following:[2]

i. Conditional core damage frequency (CCDF) (i.e., CDF because of the issue) is high (e.g., greater than or on the order of $1x10^{-3}$/year).

ii. Conditional large early release frequency (CLERF) is high (e.g., greater than or on the order of $1x10^{-4}$/year).

To assess parameters such as CCDF and CLERF or to perform a qualitative determination, the LIC-504 team will use the nominal reliability of the potentially affected SSC as the baseline. For example, if the issue pertains to the reliability of a motor-operated valve, the average failure probability of similar motor-operated valves will be used as the baseline. The estimated revised failure probability that best reflects the degraded motor-operated valves will be used to estimate CCDF and CLERF.

After using CCDF and CLERF and other factors to determine whether immediate regulatory action to place or maintain the facility in safe condition is warranted, use of ICCDP and ICLERP may be used to risk-inform followup decisions relating to the emergent issue. For example, in some instances, ICCDP or ICLERP may be used to decide the length of enforcement discretion that may be granted to require a licensee to reestablish compliance.

If the LIC-504 team concludes that there is an immediate need to take regulatory actions beyond those called for by other existing procedures, then the team should communicate that conclusion to NRR management promptly. The basis for deciding whether immediate regulatory action is needed or not should be documented within 1 month and placed in the Agencywide Documents Access and Management System (ADAMS). That document should provide quantitative (most likely a bounding analysis) or qualitative information that demonstrates that the issue does not exceed the thresholds.

Under certain circumstances, even if the LIC-504 team concludes that an immediate regulatory action is unnecessary, it may be important to inform senior management about that conclusion as soon as possible. For example, if the risk analysis includes significant uncertainties or key assumptions due to limited information, and there is a potential to receive new information that could significantly alter risk insights, notifying the senior management and documenting such uncertainties, key assumptions, and the technical and regulatory basis for the decision is critical. The LIC-504 team should be mindful of limitations associated with RIDM and, in general, decision error traps (see Refs. 13 and 14) when recommending and documenting decisions with respect to the need for prompt regulatory actions.

4.2.2. Exiting LIC-504 When the Issue Is Clearly of Very Low Safety Significance

The next step is to determine whether the issue is of very low safety significance. The objective of this step is to minimize LIC-504-related resources on issues of very low

[2] The CCDF (CLERF)) is the core damage frequency (CDF) (large early release frequency (LERF)) evaluated with consideration of the impact of the issue: it represents the height of the CDF spike. The incremental conditional core damage probability (ICCDP) (incremental conditional large early release probability (ICLERP)) is the area under the risk spike above the average CDF(LERF) level corresponding to the duration of the impact of the issue.

safety significance, without losing key insights and the need for appropriate documentation. As explained in Section 4.2.1, the team will use the nominal reliability of the potentially affected SSC to make the qualitative or quantitative determination that the issue is clearly of very low safety significance.

After entering LIC-504, if the team concludes that the safety concern can be considered of very low safety significance, it can exit the process after it documents the basis for that conclusion. To decide that the issue is of very low safety significance and to exit LIC-504, the team can use the qualitative or quantitative analyses to show that the quantified risk is very small. For the purposes of LIC-504, $\Delta CDF < 1x10^{-6}$ per reactor year and $\Delta LERF < 1x10^{-7}$ per reactor year[3] serve as thresholds to show that issues are of very low risk significance. These thresholds, in combination with an assessment of the degradation of plantwide defense in depth or safety margin, are used to determine whether an issue may be characterized as having very low safety significance. In other words, for an issue to be characterized as having "very low safety significance," in addition to meeting that ΔCDF and $\Delta LERF$ thresholds, the team should ascertain that degradations to safety margins and defense in depth are minimal. Considering the risk significance (numerical values) as well as defense in depth and safety margins is very important when LIC-504 analyzes issues that pertain to SSCs whose performance is important only to initiators with very low frequencies (e.g., barriers to external flooding).

Note that the numerical thresholds chosen in LIC-504 are the same as the GREEN\WHITE threshold used in the significance determination process in the Reactor Oversight Process. In the significance determination process, GREEN issues are characterized as having "VERY LOW SAFETY OR SECURITY SIGNIFICANCE." RG 1.174 also characterizes issues having $\Delta CDF < 1x10^{-6}$ per reactor year or $\Delta LERF < 1x10^{-7}$ per reactor year as having a "very small" increase in risk.

The best available information and tools can be used to demonstrate that the issue is of very low significance. Since there is always a potential for issues of very low safety significance to accumulate (sometimes in a synergistic manner), it is important to use demonstrably conservative calculations in showing that ΔCDF associated with the emerging issue is less that $1x10^{-6}$ per reactor year. Also, it is important to note that, due to various uncertainties, a conclusion of very low significance, in itself, should not lead to a determination that performance monitoring is unnecessary. For example, for issues with very low safety significance, performance monitoring may be necessary if the safety significance of the issue has the potential to increase with time (e.g., degradation has the potential to exacerbate because it may be time dependent).

When quantifications are not possible, qualitative analysis may be used to analyze and document whether an issue can be characterized as having very low safety significance.

Even if the issue is determined to have very low safety significance, the team should document the information and analyses used to reach this conclusion and communicate them to management and the process owner who requested the LIC-504 analysis within 3 months and then placed in ADAMS. For these instances, there is no need to follow any templates provided in Appendices B, C, and D to LIC-504. The primary objective should be to clearly document, using quantitative or qualitative information, the bases for concluding that the issue is of very low safety significance. If necessary (e.g., there are

[3] ΔCDF and $\Delta LERF$ are the estimated increases in CDF and LERF due to the emerging issue, respectively.

uncertainties), the team may recommend performance monitoring strategies. The LIC-504 team may communicate to management that it may exercise any practical options that are commensurate with the very low safety significance and consistent with higher tier process requirements.

4.2.3 Adjusting Range of Options Using Safety Significance

The LIC-504 team may use the safety significance of an issue as a basis to recommend followup options to management to optimize the benefit of the risk-informed insights resulting from an LIC 504 analysis. Figure 3 suggests guidance that the LIC-504 team may follow to screen in or screen out options based on safety significance. This table is similar in concept to guidance provided in MD 8.3, "NRC Incident Investigation Program," dated June 25, 2014 (Ref. 25), which takes a progressive approach to investigative response using a risk-informed approach. In MD 8.3, the decision on an "investigatory response" for a significant event is defined by the event's safety significance, complexity, and generic safety or security implications. It is very important to note that, albeit the similarity of concept (graded response), there is a significant difference between MD 8.3 and Figure 3. Whereas MD 8.3 uses conditional core damage probability (CCDP) associated with an event, Figure 3 uses change in CDF associated with potential degraded conditions.

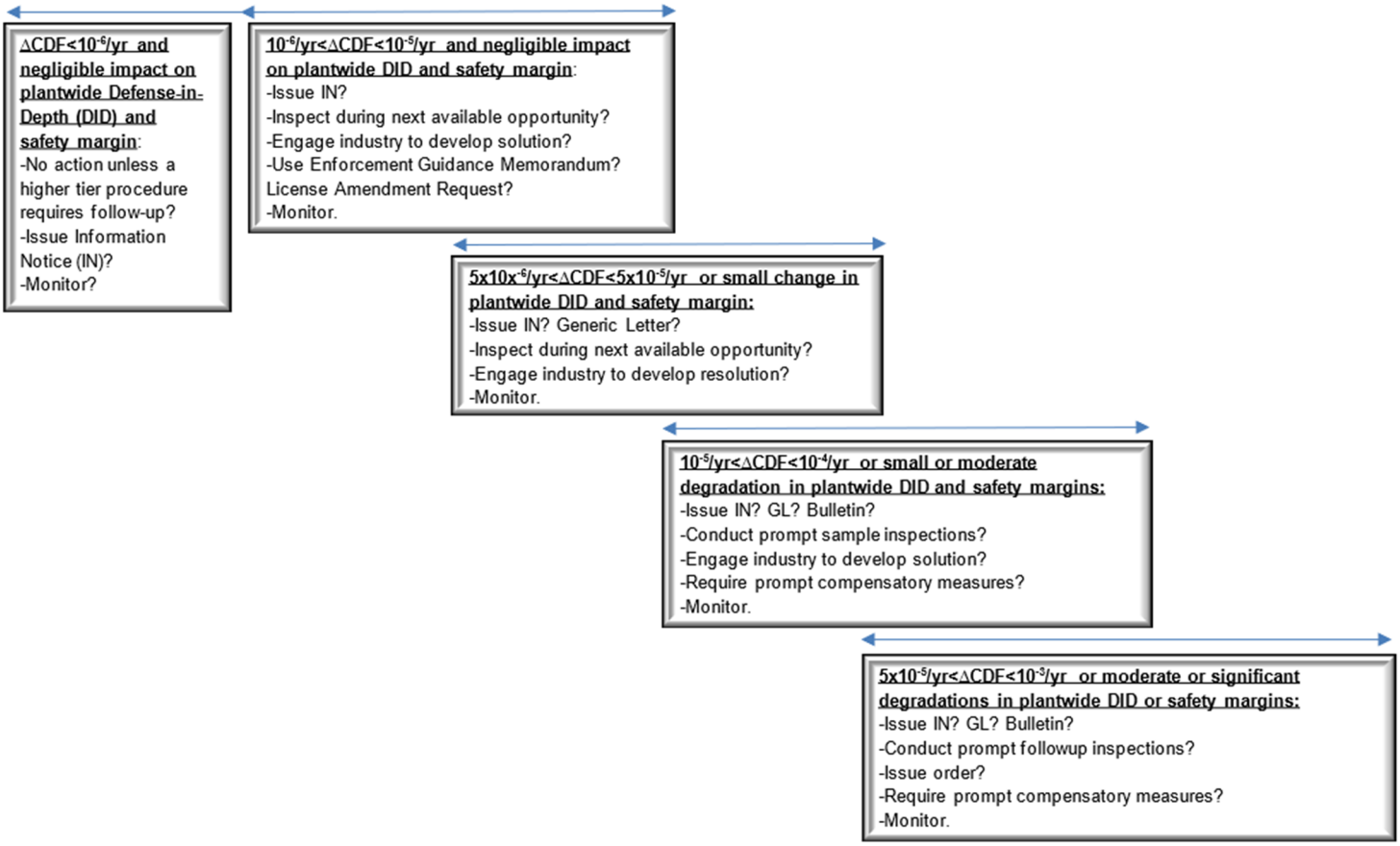

Figure 3 Example of range of regulatory options based on safety significance

4.2.4 Need for Communication Plan

For some emergent issues, if using the standard or detailed approach, a formal communication plan may be needed the following several situations:

- when an NRC project or an event is controversial or highly visible and could provoke a significant reaction from stakeholders
- when public safety, security, or preparedness could be significantly affected, or perceived to be affected
- when the results of a decision will affect the interests of some people or groups more than others (environmentally, economically, politically, or socially)
- when a project, program, or event requires careful timing, coordination, and communication to many stakeholders
- when communication with a licensee is likely through multiple NRC sources, such as multiple offices responding through different processes
- when lack of a communication plan may result in misunderstanding among key stakeholders about the intent of an LIC-504 analysis

4.2.5 Selecting the Simplified, Standard, or Detailed Approach

LIC-504 provides three approaches to evaluate issues: the “simplified approach,” the “standard approach,” and the “detailed approach.” Use of both the standard and the detailed approach can be resource intensive. Therefore, to select the appropriate approach and avoid expending undue resources, the LIC-504 team should consult with the process owner of LIC-504.

If the team concludes that the issue is not of very low safety significance, then it will continue to assess options to address the issue using either the simplified, standard, or detailed approach. Table 1 compares the high-level attributes of the three approaches.

Table 1 Different LIC-504 Approaches and Their Characteristics

Attribute	Simplified Approach	Standard Approach	Detailed Approach
Performance measure	3 months	9 months	1 year
Number of options evaluated	One or two	Multiple	Multiple
Communication plan	Not necessary	Unlikely to be necessary	May be necessary
Detailed documentation of merits\demerits of options	Not necessary	Unlikely to be necessary	May be necessary
Documentation of conclusion	Memorandum to management providing staff view of the option management proposed (with additional recommendations if necessary), or staff recommendation of one of the two options that management proposed with a brief summary of basis	Memorandum to management that summarizes each option considered, the implications on RG 1.174 principles, and other factors considered	Same as for the standard approach. However, details of the merits and demerits of each option considered should be documented with high quality and be available for release to key public stakeholders.
Management approval			Management approval is necessary for use of detailed approach

If the LIC-504 team concludes that the issue is not of very low significance, it should determine whether circumstances warrant use of the simplified approach described in Appendix B. The simplified approach is appropriate under two circumstances: (1) Because of the need for prompt regulatory action, NRC management has decided to take an action using engineering judgment (e.g., follow up with an inspection at the next outage) and wishes to evaluate and, if necessary, adjust that response using risk insights, or (2) NRC management wishes to compare two practical alternatives to select the appropriate option and document the basis for that decision. Use of the simplified approach can be less resource intensive than the other approaches, in part, because it obviates the need to evaluate and compare options that are deemed inappropriate or impractical based on informed engineering judgment. For example, as discussed in "Technical Assessment of Potential Control Rod Drive Mechanism Thermal Sleeve Failure," issued September 2018 (Ref. 26), the primary objective was to determine whether prompt inspections were needed or whether the safety significance of the issue could allow the staff to schedule its followup activities to align with planned outages of potentially affected plants.

If the team does not select the simplified approach, it should choose the standard approach described in Appendix C or the detailed approach described in Appendix D. Use of the Appendix D approach requires management approval.

The team may select the detailed approach if there is a need for highly deliberative decision process. That is, the detailed approach is useful when a structured assessment and clear documentation of the five key principles of RIDM (see Section 4.1 of this office instruction) is needed. For example, if an issue is of interest to multiple stakeholders (e.g., the Commission, Congress, State governments) or has the potential to generate significant public interest, the formality and rigor of the detailed approach might assist in formulating a very clear documentation of the decision.

Irrespective of the approach chosen, the items to be considered, report formats, and content suggestions in the appendices should be taken as guidance rather than as procedural requirements. In other words, the level of analysis and documentation should be commensurate with the significance of the emergent issue and corresponding decision to be made. The forms in the appendices may be used or modified as desired.

4.3 The Risk-Informed Decisionmaking Process

Figure 4 outlines the process to be followed for RIDM for each of the approaches (simplified, standard, or detailed). This process includes seven steps, as well as the important activities of information gathering and technical analysis, which are inputs to multiple steps. An overview of these steps is provided below. Appendix B contains detailed guidance on each for the simplified approach, Appendix C for the standard approach, and Appendix D for the detailed approach. Note that it is not essential for RIDM to have a PRA model. For example, research reactors may use the guidance in Appendices B, C, and D for an integrated risk-informed analysis.

The LIC-504 process is expected to be iterative. The need for additional information (e.g., to characterize the issue, define the options, assess the options, or integrate the results) will likely result in revisiting these steps until a recommendation can be made to the decisionmaker. The iterative nature of the process means that the analyst or team may need to loop through the process as the analysis of the issue proceeds.

Steps 1–3 in this process are similar to other RIDM processes. Information is gathered, and technical analyses are performed at this point in the process. What makes this decision process “risk-informed” is the use of the five key principles in RG 1.174 discussed in Section 4.1 of this office instruction. Steps 1–3 will likely be performed in an iterative fashion, as the technical staff identifies additional information necessary to support the analyses. The team should be mindful of the performance measures for each of the approaches when implementing the iterations.

Step 4 is also part of the RIDM process (e.g., the integrated decisionmaking step in RG 1.174). This office instruction provides additional guidance in Appendices B, C, and D for integrating the various factors that will influence the ultimate decision on the action to be taken to address the emergent issue for LIC-504 purposes.

RG 1.174 provides five principles of risk-informed integrated decisionmaking with a sole focus on public safety. These principles, however, may not capture another primary objective of the NRC’s regulations, which is the regulatory requirement for minimizing unnecessary radiation exposure to radiation workers. The doses that workers may incur cannot be used to justify not performing activities that a licensee is required to perform to

comply with regulatory requirements or address issues important to public safety. However, in some circumstances (e.g., issues of very low safety significance), LIC-504 should consider the radiation exposure as a subsidiary criterion in comparing options to address emerging issues.

Appendix F provides guidance on reaching a consensus that may be useful to teams weighing the relative merits of various options. In some instances, individuals may enter the NRC's nonconcurrence process as described in MD 10.158, "NRC Non-Concurrence Process," dated March 14, 2014 (Ref. 27).

Step 5 is to communicate the team's recommendations to the decision authority. The purpose of this step is to provide the decisionmakers with the information they need to make a properly informed decision. Typically, the decisionmaker will need a brief summary and characterization of the issue, the options considered, the recommended option, and the basis for that recommendation. The decisionmakers will also be interested in how the options and recommendation comport with the NRC's "Principles of Good Regulation" (independence, efficiency, openness, clarity, and reliability) (Ref. 28). The team should also present any recommended performance monitoring strategies at this briefing.

Step 6 is to document the final decision in a memorandum. The decisionmaker should discuss the rationale for the chosen approach for addressing the emergent issue. All affected technical branches and project manager branches should give their concurrence. If provisions for performance monitoring were deemed necessary, they should be described in the document as well. The documentation of decisions made using LIC-504 should be entered into ADAMS after redacting proprietary and safeguards information.

Step 7 is to communicate the decision to affected and interested parties. If the team developed a communication plan, then it will ensure that the appropriate stakeholders are informed of the decision. Useful information on communicating risk information may be found in NUREG/BR-0318, "Effective Risk Communication—Guidelines for Internal Risk Communication," dated December 31, 2004 (Ref. 29), and in NUREG/BR-0308, "Effective Risk Communication—The Nuclear Regulatory Commission's Guidelines for External Risk Communication," dated February 29, 2004 (Ref. 30).

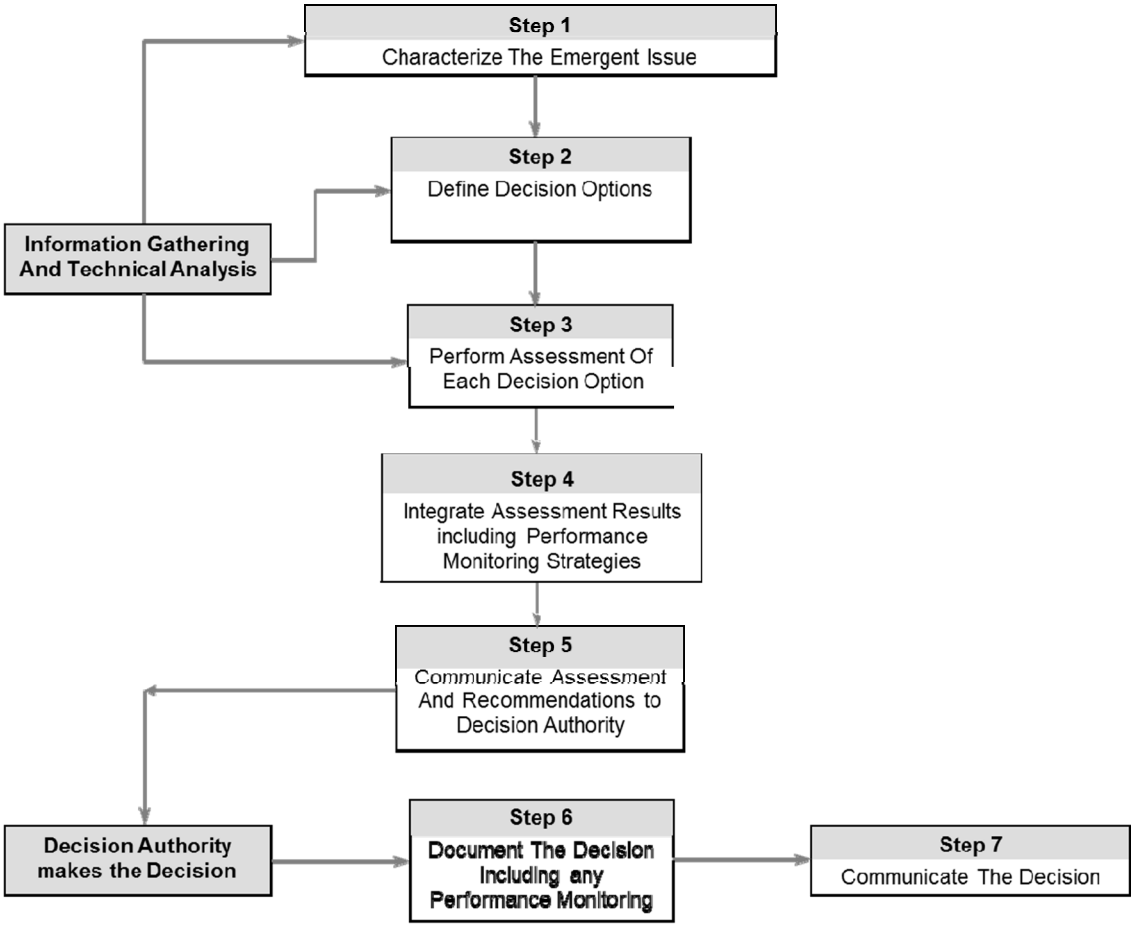

Figure 4: Process for risk-informed decisionmaking and documenting options

Underlying all steps in the process is the need for documentation. Appendices B, C, and D provide templates for documenting the decisionmaking process for the simplified, standard, and detailed approaches, respectively. The purpose of the templates is to enable and structure deliberate thinking and analysis. Use of these templates is optional.

The resulting report should document the emergent issue, options considered, bases for the recommended option, the individuals involved in the decisionmaking, and the decision that was ultimately reached. Whether the LIC-504 process is fully implemented or truncated, documentation of the effort is important. For example, a decision to maintain the "status quo" (i.e., decide that no NRC action is required) should be documented with appropriate bases.

To be effective in communicating risk-informed decisions, it is important to consider early in the process who needs to be informed and involved, as well as who will be affected, and to build in communication steps that encourage discussion and clarification throughout the process. When a communication plan is warranted, it should be developed early in the process. This enables analysts and decisionmakers to be prepared for communication activities during and at the end of this risk-informed process. Emphasizing communication during the process will help identify topics that require clarification by the staff and focus attention on ensuring that all participants

understand the subject, objective, terms, and assumptions at hand; this will encourage discussion and prevent misunderstandings among team members and enable everyone to stay on track. This is especially important when working with multidisciplinary teams that include both risk analysts and analysts from other (e.g., engineering and licensing) disciplines. The NRC's Risk Communication Guidelines (Refs. 25 and 26) emphasize the importance of explicitly addressing communication challenges early in a process.

Final documentation developed as part of this process should be placed in ADAMS for appropriate distribution.

5. RESPONSIBILITIES AND AUTHORITIES

NRR Managers

All NRR managers should be aware of the entry conditions for this office instruction as set forth in Section 4.2.

All NRR managers should also ensure that their staff follows this office instruction and, when appropriate, propose revisions to it.

Management Lead

Any NRR staff member may propose the need to perform an LIC-504 analysis to an NRR Branch Chief or an NRR Division Director. Because LIC-504 analyses may require the use of staff resources, a Division Director must approve initiation of an LIC-504 analysis. In general, the Division Director who approved the initiation of an LIC-504 analysis or his\her designee assumes the role of management lead.

The management lead is responsible for the identification and use of resources in support of the LIC-504 process. The management lead will work with the technical lead and the responsible PM to maintain the process schedule and milestones. The management lead will facilitate the communication of status, resource concerns, or constraints to senior management. If regional support is necessary, the management lead will work with the appropriate regional manager to request such support. (Note that if information needs would place excessive burden on the affected region, as determined by the regional manager, the management lead should consider other means of obtaining such information (e.g., a request for information under 10 CFR 50.54(f).)

The management lead is responsible for ensuring that, if information suggests an immediate safety concern, appropriate communications and measures are taken to ensure the safe operation of any affected facility.

The management lead is also responsible for completing the deliverables within the prescribed performance goals.

The management lead should create appropriate tracking mechanisms (e.g., Yellow Tickets) to track and manage progress.

Responsible Project Manager

The PM responsible for either the affected site or process is responsible for coordinating review and resolution activities. The PM will pull a Cost Activity Code and Enterprise Project Identifier number to ensure fee recovery and support tracking of work activities. Consistent with MD 3.5, "Attendance at NRC Staff-Sponsored Meetings," dated December 4, 2019 (Ref. 31), and COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants" (Ref. 32), the PM will ensure proper documentation of interim and final decisions made in meetings. This may require the development of a communication plan, an action plan, or both. In addition, the PM will support the development and concurrence of the LIC-504 report; he or she is also responsible for coordinating with other offices and the regions and for supporting the technical lead in the coordination of technical resources from other offices.

Technical Lead

When assigned to be a technical lead for an issue where LIC-504 is implemented, he or she will recommend to the cognizant manager the detailed approach, if deemed necessary. The technical lead will coordinate and document the technical review for that issue. The technical lead will be responsible for coordinating with the responsible PM and other offices, as applicable, to ensure technical consistency.

Regional Manager

The decision process for some emergent issues may benefit significantly from information provided by the affected regional office. The management lead for the issue may ask the regional manager responsible for the affected site to provide specific information regarding plant status or operation. The responsible PM for the site should coordinate these interactions. Participation by regional staff in support of the LIC-504 is at the discretion of the regional manager. Requests for regional support should be made to the responsible regional manager and structured so as not to adversely affect the inspection staff's ability to perform required inspection activities.

Team Members

All NRR staff members who are assigned as members of the LIC-504 team should read and understand the process and fully participate in the steps described in this office instruction. The staff should also report to the primary contact any problems with, or possible improvements to, this office instruction.

Primary Contact for This Office Instruction

The primary contact (process owner of LIC-504) is responsible for giving advice on how to use this office instruction and for monitoring the staff's use of it. The primary contact interfaces with the staff, management, and others to identify problems with, corrections to, and improvements to this office instruction. The primary contact is the routine interface between NRR and other organizations or individuals (within the NRC, industry, or the public) for this office instruction. The primary contact is responsible for carrying out and documenting periodic reviews of this office instruction.

Responsible Manager for This Office Instruction

The Director of DRA is the manager responsible for this office instruction and for developing, implementing, and maintaining it. The responsible manager may, as necessary, reassign or coordinate the reassignment of this office instruction to a different primary contact and may approve minor revisions. The responsible manager will ensure the completion of any required periodic review and will approve the review by concurring in the required documentation.

6. PERFORMANCE MEASURES

The objective of this office instruction is to ensure that RIDM activities within the scope of this instruction are coordinated and integrated such that the performance measures identified in the Strategic Plan can be met and NRR resources used efficiently and effectively.

The team must convey to responsible management as soon as practical whether immediate regulatory actions beyond those required by other existing processes (e.g., an inspection may reveal an issue that has the potential to challenge adequate protection and yet the plant may be in compliance with regulatory requirements) are warranted, based on risk-informed information, and it must document this decision **within 1 month** of entry into LIC-504.

When the team chooses the simplified approach, or the issue is of very low safety significance, based on a bounding quantitative or a qualitative analysis, the team must exit LIC-504 after documenting the basis of the decision **within 3 months** of entry into the process. The need to gather critical information essential to document the decision may alter this target.

When the team uses the standard approach, it must exit LIC-504 after documenting the basis of the decision **within 9 months after** entry into the process. The need to gather critical information essential to document the decision may alter this target.

When the team selects the detailed approach, it must exit LIC-504 after documenting the basis of the decision **within 1 year after** entry into the process. The need to gather critical information essential to document the decision may alter this target.

In the event the LIC-504 team concludes that it is unable to complete LIC-504 analysis (document and convey its recommendation to the management lead) within the time frames noted above, the team lead should inform the management lead.

As emphasized above, all performance measures are established for documenting the basis of the decision. With respect to immediate regulatory actions, they must be conveyed to decisionmakers as soon as practical, whereas there is 1 month to document the basis for that input. For longer term activities, the resolution of the issue may take much longer than the performance measure.

7. PRIMARY CONTACT

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Sunil.weerakkody@nrc.gov
(301) 415-2870

8. RESPONSIBLE ORGANIZATION

NRR/DRA

9. EFFECTIVE DATE

March 9, 2020

10. CERTIFICATION DATE

March 9, 2025

11. REFERENCES

1. NUREG-1614, Vol. 7, “Strategic Plan: Fiscal Years 2018–2022,” U.S. Nuclear Regulatory Commission, February 2012 (ADAMS Accession No. ML18032A561)

2. Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 *Federal Register* 42622; August 16, 1995).

3. SRM-SECY-98-144, “White Paper on Risk-Informed and Performance-Based Regulation,” U.S. Nuclear Regulatory Commission, March 1, 1999 (ADAMS Accession No. ML003753601).

4. SRM-M170511, “Staff Requirements—Briefing on Risk-Informed Regulation,” U.S. Nuclear Regulatory Commission, June 26, 2017 (ADAMS Accession No. ML17177A397).

5. SECY-17-0112, “Plans for Increasing Staff Capabilities To Use Risk Information in Decision-Making Activities,” U.S. Nuclear Regulatory Commission, November 13, 2017 (ADAMS Accession No. ML17270A192).

6. “Action Plan, Risk-Informed Decision-Making Operating Reactor Business Line,” U.S. Nuclear Regulatory Commission, November 27, 2018 (ADAMS Accession No. ML18317A117.

7. NRC Inspection Manual Chapter 0609, “Significance Determination Process,” U.S. Nuclear Regulatory Commission, January 1, 2019 (ADAMS Accession No. ML18187A187).

8. NRR Office Instruction LIC-106, “Issuance of Safety Orders,” U.S. Nuclear Regulatory Commission, December 17, 2003 (ADAMS Accession No. ML032590319).

9. NRC Management Directive 9.27, “Organization and Functions, Office of Nuclear Reactor Regulation,” U.S. Nuclear Regulatory Commission, January 24, 2017 (ADAMS Accession No. ML16319A215).

10. GAO-04-415, “Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant’s Shutdown,” U.S. General Accounting Office, May 5, 2004.

11. “Nuclear Regulatory Commission Enforcement Manual,” Rev. 10, Change 2, U.S. Nuclear Regulatory Commission, April 30, 2018 (ADAMS Accession No. ML18018B134).

12. NRC Inspection Manual Chapter 0350, “Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns,” dated March 1, 2018.

13. Review of Fort Calhoun Site Flooding Issues in Accordance with Office of Nuclear Reactor Regulation Office Instruction LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues,” November 2013, U.S. Nuclear Regulatory Commission (ADAMS Accession No. ML13058A352).

14. NRC Probability Risk Assessment Training Course P-109, “Assessing the Adequacy of Models for Risk-Informed Decisions,” U.S. Nuclear Regulatory Commission, March 2019.

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16. NRC Regulatory Guide 1.174, Rev. 3, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” U.S. Nuclear Regulatory Commission, January 2018 (ADAMS Accession No. ML17317A256).

17. OMB Circular No: A-123, “Management’s Responsibility for Enterprise Risk Management and Internal Control,” Office of Management and Budget, July 15, 2016.

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19. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” Chapter 19, “Severe Accidents,” Section 19.2, “Review of Risk Information Used To Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance,” U.S. Nuclear Regulatory Commission, June 2007 (ADAMS Accession No. ML071700658).

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Information Collection,'" U.S. Nuclear Regulatory Commission, May 29, 2019 (ADAMS Accession No. ML19149A294).

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22. Title 10, "Energy," *Code of Federal Regulations (*10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.65, "Requirements for Monitoring the Maintenance Effectiveness at Nuclear Power Plants."

23. NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," Vol. 1, "Main Report," U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525).

24. NRC Regulatory Guide 1.200, Revision 2, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090410014).

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26. "Technical Assessment of Potential Control Rod Drive Mechanism Thermal Sleeve Failure," Documentation of Integrated Risk-Informed Decision-Making Process in Accordance with LIC-504, U.S. Nuclear Regulatory Commission, September 2018 (ADAMS Accession No. ML18249A081).

27. NRC Management Directive 10.158, "NRC Non-Concurrence Process," U.S. Nuclear Regulatory Commission, March 14, 2014 (ADAMS Accession No. ML18073A296).

28. "Principles of Good Regulation," U.S. Nuclear Regulatory Commission (ADAMS Accession No. ML14135A076).

29. NUREG/BR-0318, "Effective Risk Communication—Guidelines for Internal Risk Communication," U.S. Nuclear Regulatory Commission, December 31, 2004 (ADAMS Accession No. ML050960339).

30. NUREG/BR-0308, "Effective Risk Communication—The Nuclear Regulatory Commission's Guidelines for External Risk Communication," U.S. Nuclear Regulatory Commission, February 29, 2004 (ADAMS Accession No. ML040690412).

31. NRC Management Directive 3.5, "Attendance at NRC Staff-Sponsored Meetings," U.S. Nuclear Regulatory Commission, December 4, 2019.

32. COM-203, Revision 2, “Informal Interfacing and Exchange of Information with Licensees and Applicants,” U.S. Nuclear Regulatory Commission, April 13, 2009 (ADAMS Accession No. ML082940232).

Enclosures:

1. Appendix A: Change History
2. Appendix B: Simplified Approach to Risk-Informed Decisionmaking
3. Appendix C: Standard Approach to Risk-Informed Decisionmaking
4. Appendix D: Detailed Approach to Risk-Informed Decisionmaking
5. Appendix E: Risk-Informed Principles Evaluation Worksheet
6. Appendix F: Reaching Consensus on a Recommendation

Appendix A
Change History

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process
for Emergent Issues

LIC-504—Change History			
Date	Description of Changes	Method Used to Announce & Distribute	Training
10/31/2005	Changes: This is initial issuance of LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues." The objective of this office instruction is to outline a process by which the Office of Nuclear Reactor Regulation (NRR) staff and managers perform the evaluation and communication of risk-informed decisions and thereby improve NRR's efficiency and effectiveness.	Email to all staff	Training of affected staff within 6 months of issue date by organizational units
12/20/2005	Changes: This is Revision 1 of LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues." Revision 1. Clarification of regulatory actions in Section 4.6.1.	Email to all staff	N/A
02/22/2007	Changes: (1) Issued for use (not trial use); (2) Major change in format of appendices in Enclosure 2 to incorporate feedback from a Table Top exercise conducted in 2006.	Email to all staff	Training of selected staff and management by DRA within 6 months of issue date.
04/07/2010	This revision incorporates feedback and comments received after using this procedure to support decision-making in an actual emergent issue (documented in ADAMS ML070990071 and ML081580560). The conditions for entering LIC-504 have been clarified. A "standard approach" and "detailed approach" are provided to allow the user flexibility to tailor the process for a given issue.	Email to all staff	Self-study

LIC-504—Change History			
Date	Description of Changes	Method Used to Announce & Distribute	Training
05/30/2014	Revision 4 incorporates lessons from increasing use of this office instruction for a number of emergent issues. The conditions for entering into this office instruction have been further clarified and additional guidance on performance monitoring has been added. A new section has been added to more fully describe the risk-informed approach to regulatory decision-making. Specifically, changes were made in the following areas: a. Strategies in the “policy” section updated to match current Strategic Plan. b. A new section (Section 4.1) was added to more fully describe the risk-informed approach to regulatory decision-making and the other sections re-numbered. c. The discussion regarding communication plans was elevated to a sub-section (4.2.4) and is also now only an option when using the standard or detailed approach. d. Figure 2 was greatly simplified and now provides examples of “other processes” that would result in not entering LIC-504. e. The entry to LIC-504 was changed to always start with the “standard approach.” The user may progress to the “detailed approach” as the analysis proceeds and if warranted. f. Figure 2 was revised to show the actual decision being made and to refer to “performance monitoring.” g. The relationship of LIC-504 to the non-concurrence process is discussed. h. References were updated or added for completeness. i. Attachments 1 and 2 to Appendix C were re-named Appendix D and E, respectively. j. Other editorial changes were made to improve readability.	Email to all staff	Self-study

LIC-504—Change History			
Date	Description of Changes	Method Used to Announce & Distribute	Training
03/04/2020	Revision 5 incorporates lessons from increasing use of this office instruction for a number of emergent issues since the issuance of Revision 4 in 2014. a. Revision 5 establishes a "simplified" approach to performing the LIC-504 assessment. It has been added to enable the staff to perform LIC-504 analyses for noncomplex issues in a timely manner without using excessive resources. b. Revision 5 establishes performance measures for completion for LIC-504 deliverables. c. Revision 5 addresses a lesson learned during the Anchor-Darling LIC-504 analysis. This revision emphasizes that when concerns or issues have generic implications (e.g., operability), NRR is best suited to lead the resolution of the issue for all affected stakeholders, using existing processes designed to address generic implications. d. Revision 5 adds potential radiation exposure to workers as a subsidiary criterion to supplement risk-informed decisionmaking (RIDM) consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," for radiation workers. Furthermore, this change will make the LIC-504 approach more consistent with regulatory practices used for fuel facilities, as given in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." e. Revision 5 acknowledges that LIC-504 may be used even when other NRC processes or procedures may exist to resolve the issue (e.g., technical specification compliance, inspection and enforcement, potential noncompliance) and clarifies the role of LIC-504 compared to other existing procedures. f. Revision 5 changes the ΔCDF threshold for very low risk significance issues from $1x10^{7}$/year to $1x\ 10^{-6}$/year and the ΔLERF threshold for very low significance issues from $1x10^{-8}$/year to $1x10^{-7}$/year.	E-mail to all staff	Self-study

LIC-504—Change History			
Date	Description of Changes	Method Used to Announce & Distribute	Training
	g. Revision 5 reduces documentation burdens on the LIC-504 team when an issue is of very low safety significance. h. The need to use risk analysis as described in Regulatory Guide (RG) 1.200, to support LIC-504 is deemphasized, since LIC-504 analysis does not require RG 1.200 quality probabilistic risk assessment models. i. Figure 2 has been replaced since it is inconsistent with practice. The new figure shows the entry and exit of LIC-504 for each of the three approaches. j. Revision 5 removes references to Δ conditional core damage frequency and uses ΔCDF instead. k. Revision 5 highlights traps in risk-informed decisionmaking and directs the reader's attention to course material in P-109 to increase awareness of this issue. l. Revision 5 provides additional guidance on how to treat uncertainties and key assumptions in risk-informed decisionmaking using NUREG-1855. m. Revision 5 contains additional guidance on how to use RG 1.174, which is primarily intended for the review of licensing actions in evaluating emerging issues. n. Revision 5 notes that LIC-504 may be used to resolve issues relating to research and test reactors. o. Revision 5 refers to RIDM and SECY-98-0144. p. Revision 5 removed references to ICCDP and ICLERP as numerical thresholds that can be used to estimate the duration of enforcement discretion.		

Appendix B

Simplified Approach to Risk-Informed Decisionmaking

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process for Emergent Issues

The U.S. Nuclear Regulatory Commission (NRC) recommends following the steps described below when applying the simplified approach of LIC-504 to an emergent issue.

Initiate the LIC-504 Process

The simplified approach is appropriate under two circumstances: (1) NRC management has decided to take a particular regulatory action using engineering judgment because of the time-critical nature of the regulatory response and wishes to evaluate and, if necessary, adjust that response, and (2) NRC management wishes to evaluate two practical alternatives to select the appropriate option and document the basis for that decision.

Identify the decision authority—This is the individual or NRC organization that will make the decision. Depending on the decision, potential decisionmakers include Branch Chiefs, Division Directors, a risk-informed licensing panel, Office Directors/Regional Administrators, or the NRC Executive Director for Operations. In the simplified approach, the decision authority will identify one or two options that the LIC-504 team must assess.

Identify the NRC organizations involved in supporting the decision—Consider the functions and analysts (e.g., the technical areas of expertise) needed to conduct the analysis.

Name a management lead for the effort—This will normally be a Division Director or Branch Chief in the organization that has primary responsibility for resolving the issue. The management lead should do the following:

- Identify the project manager and name a technical lead.
- Ensure that an adequate technical team is formed. This includes obtaining sufficient resources to characterize the issue, define options, perform the analyses, and make a recommendation.
- Determine whether regional support is needed. The management lead will request appropriate support from the applicable region.
- Set expectations for the team, such as (1) team member participation has a high priority, (2) a sufficient number of team meetings will be held to facilitate process integration, and (3) documentation should be developed concurrently with the decision. The expectations should include a schedule for presenting the team's recommendation to the decision authority.

Table B-1 provides a convenient form for documenting the initiation of the LIC-504 process.

Perform Steps 1–4 of the Risk-Informed Decisionmaking Process (Figure 4)

The technical lead (and team, if applicable) performs the first four steps of the risk-informed decisionmaking process (Figure 4 of LIC-504) and captures the results of each step (e.g., working notes, document files, analysis files) to aid in documenting the decision in Step 5 (Step 6 of Figure 4).

Characterize the Emergent Issue (Step 1)

The purpose of this step is to characterize the issue in terms of the physical impact on the plant and the potential impact on safe operation, including the possible impact on human actions (e.g., through procedures), well enough to begin the development of options (next step).

Sample tasks in this step include the following:

- identifying the structures, systems, and components or operational characteristics affected by the issue (including human actions)
- describing the nature of the effect on the identified structures, systems, and components or operational characteristics
- documenting the potential impacts of the issue on the safe operation of the plant
- identifying the regulations (or other requirements or commitments, such as design basis, licensing basis, generic letters) that this issue may challenge

The technical lead (or team, if applicable) should consider any source of information expected to provide accurate and useful information bearing on the issue.

Define Decision Options (Step 2)

For the simplified approach, there is no need to execute this step because the one or two options that will be considered have been predetermined for the team.

Perform Assessment of the Decision Option or Options (Step 3)

In this step, the technical staff assigned to work on this issue will analyze and document the assessment of the one or two options that have been chosen, or the two options that were considered as practical, using key principles of risk-informed decisionmaking.

While the factors used in the simplified approach may coincide with the five key principles of risk-informed decisionmaking, there may be issues for which some other factor is the key to the decision. Examples of other factors may include (1) amount of time a degraded condition would remain uncorrected, (2) degree of uncertainty from one option to another, (3) relative impact on public confidence, (4) relative burden to licensees, and (5) potential radiation exposures a licensee may have to incur to implement the option.

Integrate Assessment Results and Determine Performance Monitoring Strategies (Step 4)

At this point, the technical lead or team has defined and analyzed the option or options to address the emergent issue. The LIC-504 team should also consider which, if any, performance monitoring strategies are needed, along with the recommended action. Note the critical role of performance monitoring as a defense against uncertainties (this can be seen from the discussion in the main body of NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," issued March 2009) (Ref. B.1). The purpose of performance monitoring is to verify that the action taken to address the issue actually has the intended result and that no adverse, unintended consequences arise. Performance monitoring may include additional NRC oversight, periodic reporting of selected parameters by the licensee, or similar measures.

Perform Steps 5–7 of the Risk-Informed Decisionmaking Process (Figure 4)

Communicate Assessment and Recommendations to the Decision Authority (Step 5)

The purpose of this step is to provide the decisionmakers with the team's conclusion with a summary of the basis for that conclusion. For situations in which the team considered two options, it should document and convey its conclusion with respect to the recommended option. For situations in which it assesses a decision made by management using engineering judgment, the team should give its independent view. In evaluating options, the decisionmakers will also be interested in how the options and recommendation agree with NRC's Principles of Good Regulation (independence, efficiency, openness, clarity, and reliability). This could range from (1) confirming the validity of the decision, (2) recommending an enhancement of the decision (e.g., suggesting performance monitoring), or (3) recommending that a different option be pursued.

Document the Decision, Including Performance Monitoring (Step 6 of Figure 4)

Once the team makes the final decision, it should document it in a memorandum or other communication. The decisionmaker should discuss the rationale for the approach chosen to address the emergent issue. The document should also describe any provisions for performance monitoring deemed necessary. In most instances, the team's recommendation, prepared in Step 5, with appropriate modification, may be sufficient to complete Step 6.

Communicate the Decision (Step 7)

Step 7 is included to reemphasize the need to share the staff decision with all internal and external stakeholders using appropriate means (e.g., orally, e-mail).

REREFERENCE FOR APPENDIX B

B.1. NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk Informed Decision Making," Vol. 1, "Main Report," U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525).

Table B-1 LIC-504 Process Initiation

Date LIC-504 Initiated:_____ Date of Report:_____[ ] draft [ ] final			
Summary Description of Issue:			
Decision Authority	Name/Title	Organization	Telephone
Evaluation Team:	Name/Title	Organization	Telephone
Management Lead			
Project Manager			
Technical Lead			
Team Members			
ADAMS Accession No. _____			

Appendix C

Standard Approach to Risk-Informed Decisionmaking

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process for Emergent Issues

Once it has been decided to enter LIC-504, if the simple approach is not appropriate, the process then goes to the standard approach, as described in this appendix. As the analysis of the emergent issue proceeds, the management lead may decide that the additional detail provided in the detailed approach (described in Appendix D) is warranted. The team would continue working to resolve the issue but would use the more detailed forms in Appendix D to structure the analysis of the various options.

The U.S. Nuclear Regulatory Commission (NRC) recommends the following steps when applying the standard approach of LIC-504 to an emergent issue.

Initiate the LIC-504 Process

The process to initiate the standard approach for LIC-504 is identical to the process used for the simplified approach. The key exception is that the LIC-504 team will expend additional efforts to identify various options for resolving the issue within the constraints of any NRC processes or procedures that have higher priority.

Another difference is the need to decide whether a communication plan is necessary, and, if so, to designate a communications lead (usually the project manager). This individual should coordinate with the Office of Public Affairs for issues of high stakeholder interest, as appropriate. (Refer to Section 4.2.4 in the body of this office instruction.)

Table B-1 in Appendix B is a convenient form for documenting the initiation of the LIC-504 process.

Perform Steps 1–4 of the Risk-Informed Decisionmaking Process (Figure 4)

The technical lead (and team, if applicable) performs the first four steps of the risk-informed decisionmaking process (Figure 4 of LIC-504) and capture the results of each step (e.g., working notes, document files, analysis files) to aid in documenting the decision in Step 5 (Step 6 of Figure 4).

Characterize the Emergent Issue (Step 1)

This step should be implemented in a manner similar to the first step in the simplified approach.

Define Decision Options (Step 2)

The purpose of this step is to define the decisionmaking environment, to develop the decision options, and to describe the decision criteria for evaluating the options. The LIC-504 team should carefully consider all realistic options available to resolve an issue. When higher tier processes and procedures exist, the team should be mindful of any constraints imposed by

those procedures when selecting the options. Figure 3 in the main body of the document should also be used as an input to select realistic options. For example, for an issue of low safety significance, a bulletin is not a viable option. Conversely, if an issue points to a safety concern that could significantly increase without prompt regulatory intervention, issuing a bulletin or orders, limiting restart, or communicating promptly with licensees, are options to be considered.

The decisionmaking environment includes the key boundary conditions for the assessment and consideration of the urgency, severity, and expected duration of the issue. The team should identify analysis tools and techniques applicable to the issue, including NRC-approved risk analysis methods.

A technical lead or team should develop a decision or set of options to evaluate in the decisionmaking process. For each identified option, the technical lead or team should identify the potential impact on the principles of risk-informed decisionmaking, to the extent they apply, or other factors that aid the decision process. To facilitate this evaluation, the team should select the decision criteria that will form the basis for acceptability or rejection for each decision option

Table C-1 provides a convenient format for capturing the options considered to address the emergent issue, the analysis approach, the affected principles or factors, and the evaluation criteria. Table C-1 also includes a column to document the evaluation of each option (the next step in the process). Even if the table is not filled out, it enables a structured deliberative process to capture and document available realistic options for further evaluation.

Assess Each Decision Option (Step 3)

In this step, the technical staff assigned to work on this issue will analyze and document the assessment of each option. The staff evaluates options using any consistent set of appropriate factors that differentiate one option from the others, so as to describe the rationale used to decide on the recommended option.

To the extent possible, these factors should relate to one or more of the key principles of risk-informed decision (refer to Section 4.1 of this office instruction) and address the following:

- meets current regulations
- is consistent with the defense-in-depth philosophy
- maintains sufficient safety margins
- seeks to keep increases in risk small
- uses performance measurement strategies to monitor change.

While the factors used in the standard approach may coincide with the five key principles of risk-informed decisionmaking, there may be issues for which some other factor is the key to the decision. Examples of other factors include (1) amount of time a degraded condition would remain uncorrected, (2) degree of uncertainty from one option to another, (3) the relative impact of this option on public confidence, (4) relative burden on licensees, and (5) potential radiation exposures for the licensee. There is no reason to “force fit” a discussion of noninformative factors into the documentation. Conversely, any number of other factors may be relevant to the decision. The analyst should concentrate on the relative merits of one option compared to the

others, using the factors appropriate for the particular issue. The document should be no longer than necessary to document the process that was followed.

The result of this step is a summary of the analysis for each decision option, which can be included in Table C-1. In many situations, the impact of various options on the principles of risk-informed decisionmaking, as well as other important factors such as potential exposure to the public, may be identical. In such cases, for the standard approach, it is not necessary to repeat the implications of the different options in the documentation. This is a simplification in the standard approach compared to the detailed approach in Appendix D, where each option may have an individual evaluation sheet (Table D-1). In the standard approach, this documentation may be combined.

Integrate Assessment Results and Determine Performance Monitoring Strategies (Step 4)

At this point, the technical lead or team has defined and analyzed options to address the emergent issue and must select a recommended option from the acceptable options that it has evaluated. The integration process may be as simple as providing a brief summary of the option or options and presenting the factor or factors that differentiate the preferred option from the alternatives. The "pros and cons" of each option may be one way to justify the preference of one option over another.

Comparing options and recommending an action to the decision authority can sometimes be a contentious team activity. Appendix F provides guidance on reaching a consensus that may be useful to teams weighing the relative merits of various options. In some instances, individuals may disagree and enter the process set forth in Management Directive 10.158, "NRC Non-Concurrence Process," dated March 14, 2014 (Ref. C.1).

The LIC-504 team should also consider whether the licensees have established any performance monitoring strategies. Performance monitoring plays a critical role as a defense against uncertainties (as shown in the discussion in the main body of the document on NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," issued March 2009 (Ref. C.2)). The purpose of performance monitoring is to verify that the action taken to address the issue actually has the intended result and that no adverse, unintended consequences arise. Performance monitoring may include additional NRC oversight, periodic reporting of selected parameters by the licensee, or similar measures.

Perform Steps 5–7 of the Risk-Informed Decisionmaking Process (Figure 4)

Communicate Assessment and Recommendations to the Decision Authority (Step 5 of Figure 4)

The purpose of this step is to provide the decisionmakers with the information they need to make a properly informed decision. Typically, the decisionmaker will need information presented in summary format for rapid assessment and ease of understanding the impacts and complexity of an issue. The staff may use slides or other briefing media to facilitate a meeting with the decisionmaker.

The briefing of the decisionmaker should include a brief summary and characterization of the issue, the options considered, the recommended option, and the basis for that recommendation. The decisionmakers should learn of any recommended performance monitoring strategies and

will also be interested in how the options and recommendation agree with the NRC's Principles of Good Regulation (independence, efficiency, openness, clarity, and reliability).

The decision authority, using the information provided in the briefing and any other information he or she deems relevant, decides how to address the emergent issue. The decision might be to implement the option recommended by the LIC-504, or it might be to take some other action.

The decision authority should communicate his or her basis for the decision, so that it can be documented (next step). This basis should be fairly detailed when the decision is to adopt some action other than that recommended by the LIC-504 team. This is not to second-guess the decision authority but to provide scrutable documentation of how and why a given action was taken, as recommended in the U.S. General Accounting Office (now U.S. Government Accountability Office) report GAO-04-415, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," dated May 5, 2004 (Ref. C.3).

Document the Decision, Including Performance Monitoring (Step 6 of Figure 4)

Once the staff has made the final decision, it should document it in a memorandum or other communication. The decisionmaker should discuss the rationale for the approach chosen to address the emergent issue. The document should also describe any provisions for performance monitoring.

If the issue and associated analyses warrant, the NRC may generate a report to document the process, the analyses, the integrated assessment of options, the recommendation, and the final decision. This report should not only document the decision but also any insights provided by the decisionmaker.

Table C-2 is an outline for structuring a report.

Communicate the Decision (Step 7 of Figure 4)

The decision and related information should be communicated to the management lead. If the team developed a communication plan, it should ensure that appropriate stakeholders are informed of the decision. In all cases, the documentation of decisions made using LIC-504 should be entered in the Agencywide Documents Access and Management System.

REFERENCES FOR APPENDIX C

C.1. Management Directive 10.158, "NRC Non-Concurrence Process," U.S. Nuclear Regulatory Commission, March 14, 2014 (ADAMS Accession No. ML18073A296).

C.2: NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk Informed Decision Making," Vol. 1, "Main Report," U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525).

C.3: GAO-04-415, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," U.S. General Accounting Office, May 5, 2004.

Table C-1 Decision Options

#	Option[1]	Analysis Approach[2]	Affected Principles or Factors[3]	Criteria Used To Evaluate Options[4]	Evaluation[5]

Notes:

1. Define each decision option (e.g., shut down plant immediately, shut down in specified time period, or disallow a plant from restarting).
2. Identify available analytical tools (quantitative or qualitative), such as risk analysis tools or engineering models.
3. Identify potential impact on the principles of risk-informed decisionmaking or other factors being analyzed or evaluated to differentiate the options.
4. Define the basis or standard for accepting or rejecting each decision option.
5. Compare the options and justify the option recommended for implementation.

Table C-2 Sample Report Format To Document LIC-504 Decision Process

ISSUE SUMMARY

(Provide a brief overview of the issue in sufficient detail to understand what the issue is and why a decision is needed.)

ISSUE CHARACTERIZAION

OPTIONS CONSIDERED

(Attach Table C-1, if necessary.)

EVALUATION AND ASSESSMENT OF OPTIONS

(Briefly summarize the option or options for addressing the issue. Present the factor or factors that differentiate the preferred option from alternatives, including the five principles of risk-informed decisionmaking. Include “pros and cons” for each option, as appropriate. Attach Table C-1 if used.)

RECOMMENDATION

(Compare the options and justify the option recommended for implementation.)

FINAL DECISION

PERFORMANCE MONITORING STRATEGIES (IF APPLICABLE)

ATTACHMENTS

(As needed)

Appendix D

Detailed Approach for Risk-Informed Decisionmaking

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process for Emergent Issues

Under certain circumstances, the U.S. Nuclear Regulatory Commission (NRC) staff may use the detailed approach to perform and document the LIC-504 analysis. Some circumstances that may prompt a detailed approach include the following:

- decisions that require a highly deliberative decision process, involve multiple technical disciplines or large uncertainties, or may have significant unintended consequences if an appropriate option is not chosen
- issues of significant interest or concern to key stakeholders (State Governments, Congress, the Commission)
- issues the resolution of which may have broad-reaching burdens or implications for the regulated industry

The detailed approach can be resource intensive. Therefore, the Director of the Division with lead responsibility for the issue (or the Director's designee) will make the decision to use this approach, in consultation with appropriate senior management from the Office of Nuclear Reactor Regulation and the Director of the Division of Risk Assessment. The LIC-504 team may also ask to change to a detailed approach, if warranted, as the team becomes more acquainted with the emergent issue.

Once it has been determined that the detailed approach of LIC-504 should be applied to an emergent issue, the following steps are recommended. (It is assumed here that the issue has already been characterized as described in Appendix B. The intent is to build on the work done up to the point that the team selects the detailed approach.)

Initiate the LIC-504 Process

The process to initiate the detailed approach for LIC-504 is identical to that used to initiate the standard approach. The key exception is that the LIC-504 team will expend additional efforts to identify even more detail for the various options available to resolve the issue within the constraints of any higher priority NRC processes or procedures.

Perform Steps 1–4 of the Risk-Informed Decisionmaking Process (Figure 4)

The technical lead (and team, if applicable) performs the first four steps of the risk-informed decisionmaking process shown in Figure 4 of LIC-504. The technical lead or team should capture the results of each step (e.g., working notes, document files, analysis files), to aid in documenting the decision in Step 5 below (Step 6 in Figure 4).

Characterize the Emergent Issue (Step 1)

The staff will implement this step in a manner similar to that in the simplified approach.

Define Decision Options (Step 2)

The purposes of this step are to define the decisionmaking environment, to develop the decision options, and to describe the decision criteria for evaluating the options. The team will implement this step in a manner similar to that used in the standard approach. In light of the potential for significant scrutiny from important stakeholders, the team is advised to document the bases for screening in or screening out options.

Assess Each Decision Option (Step 3)

For the detailed approach, the team's implementation of this step should be similar to that of the standard approach.

However, because of the potential for significant scrutiny of issues treated under the detailed approach, for each analysis performed, the team must document the technical adequacy of the methods, information, and data. For decisions involving passive components, the team should assess the adequacy of the specific degradation model, structural integrity model, and inspection information (Ref. D.1).

The result of this step is a summary of the analysis for each decision option. Table D-1 provides a convenient format for capturing the assessment of each option considered, including driving factors and key technical inputs.

Integrate Assessment Results and Determine Performance Monitoring Strategies (Step 4)

At this point, the team has defined and analyzed options to address the emergent issue. The team must then use the information about each option to identify whether it is acceptable or unacceptable, relative to the five principles of risk-informed decisionmaking. The team should also identify the preferred option from among the acceptable ones, including the justification for the preference. Table D-1 includes a place near the top to indicate whether a given option is preferred, acceptable, or not acceptable.

The comparison of the options using the driving factors and the selection of a preferred option can sometimes be a contentious team activity. Appendix F provides guidance on reaching a consensus that may be useful to teams weighing the relative merits of various options. In some instances, individuals may disagree and enter the NRC's process set forth in Management Directive 10.158, "NRC Non-Concurrence Process," dated March 14, 2014 (Ref. D.2).

The LIC-504 team should also consider which, if any, performance monitoring strategies are needed, along with the recommended action. Performance monitoring plays a critical role as a defense against uncertainties (as shown in the discussion in the main body of the document on NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," issued March 2009 (Ref. D.3)). The purpose of performance monitoring is to verify that the action taken to address the issue actually has the intended result and that no adverse, unintended consequences arise. Performance monitoring may include additional NRC oversight, periodic reporting of selected parameters by the licensee, or similar measures.

Table D-1 Assessment of Decision Options

Option #: Description:
Preferred [ ] Acceptable [ ] Not acceptable [ ]

Driving Factor[1]	Key Technical Inputs[2]	Characterization of the Representation of the Key Technical Input[3]	Characterization of Confidence in the Assessment of the Driving Factor[4]

Notes:

1. The driving factors are the assessments of those principles of integrated decisionmaking that play the most significant role in the decision (e.g., defense in depth, safety margin, risk). Monitoring is assumed to be part of the definition of the option when applicable. When the option is not acceptable, there need be only one driving factor. When an option is acceptable, all principles must be met. When one acceptable option is preferred over another, one of the principles may be the tie-breaker, by performing a relative assessment of meeting the principle. Other "driving factors" may exist and may be included, as appropriate, in addition to the five key principles.
2. A key technical input is an essential input to the analysis that enables the conclusion of acceptability or unacceptability to be reached. There may be several key technical inputs. For example, in assessments of the acceptability of monitoring degradation to maintain power operation, the technical inputs would be those associated with the degree and rate of degradation and the efficacy of the monitoring process.
3. Assessment of the validity and applicability of each technical input is particularly relevant when the technical input is the result of an analysis or an inference but not when the input is factual.
4. Assessment of the confidence in the assessment recognizes the uncertainties in the technical inputs.

Perform Steps 5–7 of the Risk-Informed Decisionmaking Process (Figure 4)

Communicate Assessment and Recommendations to the Decision Authority (Step 5 of Figure 4)

This step gives the decisionmakers the information they need to make a properly informed decision. The team should prepare a communication document that can convey the essential information. Although slides containing brief lists of topics can facilitate meetings, they are typically not sufficient to accurately convey and document the material that the decisionmakers will use to make the decision.

Decisionmakers typically need information presented in summary format for rapid assessment and ease of understanding the impacts and complexity of an issue. A proposed structure for this summary follows:

Background: Begin with enough background information to introduce the issue and the decision to be made. Include the summary and characterization of the issue.

Decision: Clearly and concisely state the decision required.

Options: Present each of the options developed in Steps 2 through 4 individually and concisely. Present the preferred option first. Include the driving factors for accepting or rejecting the option. Typically, these factors address the agreement or disagreement with the principles of risk-informed decisionmaking that are relevant to the issue, plus a discussion of how the degree of uncertainty (or certainty) of supporting information affects application of the principles to the option. Address any other relevant criteria. It is not sufficient to merely reference the attachments to convey the logic of the conclusions and recommendation. The presentation will use the attachments as supporting documentation, but the communication document must contain sufficient information to describe the logical basis for accepting and rejecting options. The decisionmakers will also be interested in how the options and recommendation agree with NRC's Principles of Good Regulation (independence, efficiency, openness, clarity, and reliability).

Recommendation: Summarize the logic for accepting the recommended option and rejecting other options, drawing from the discussions of the individual options. If more than one option is acceptable, explain the basis for preferring the recommended option.

Supporting Details: Briefly describe any technical issues that are particularly important for the decisionmaker to make a properly informed decision. Decisionmakers need narrative descriptions that provide qualitative insight into causes, uncertainties, assumptions, sensitivities, and affected outcomes for a given situation. Less information is needed about the details of numerical results, statistical methods, and analyses. This background information must be available, but the communication document should present it only as necessary, and only in summary form, after the recommendations. Provide references to the detailed documentation in any summaries that are included and describe how the process used NRC-approved methods.

Recommended Performance Monitoring Strategies: Provide details of recommended performance monitoring strategies needed to monitor the efficacy of any action taken to address the emergent issue.

Other Relevant Information: Provide any other relevant information, such as generic implications, stakeholder concerns, or known or anticipated impacts of a decision on other regulations.

Technical Contacts: List staff contacts for each relevant issue or input at the end of the document.

When the decisionmakers receive the above information, they may request additional information or other inputs. In particular, this may occur if the technical group could not reach a consensus recommendation in Step 4 for a preferred option. If decisionmakers identify the need for additional information or analyses, the integration team staff should return to the appropriate step in the process to refine or supplement the decision inputs.

Decision Authority Makes the Decision

The decision authority, using the information presented in the briefing and any other information he or she deems relevant to the issue, decides how to address the emergent issue. The decision might be to implement the option recommended by the LIC-504, or it might be to take some other action. The decision could even be to take no action. The decision authority should also consider any recommended performance monitoring strategies and determine what performance monitoring, if any, is needed to monitor the action he or she has approved.

It is not within the scope of LIC-504 to provide guidance to NRC managers or other individuals who are the "decision authority" on how to make decisions. One goal of the LIC-504 process is to facilitate good decisions by providing the decisionmaker with the best information available, including limitations and uncertainties in the technical analyses that support any recommendation.

The decision authority should communicate his or her basis for the decision, so that it can be documented (next step). This basis should be fairly detailed when the decision is to adopt some action other than that recommended by the LIC-504 team. This is not to second-guess the decision authority but to provide scrutable documentation of how and why a given action was taken, as recommended in the General Accounting Office (now Government Accountability Office) report GAO-04-415, "Nuclear Regulation—NRC Needs To More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," dated May 5, 2004 (Ref. D.4).

Document the Decision, Including Performance Monitoring (Step 6 of Figure 4)

Once the decision has been made, the staff should document it. This documentation should contain appropriate supplemental material to provide an archival record showing why the staff selected the option to address the issue. Documentation of the decision should include not only the decision but also the following:

- insights obtained from the decisionmaker
- how various factors were considered in reaching the final decision
- key or influential assumptions
- factors not considered in the technical analysis of the issue
- any contingencies or need for subsequent decision points

- performance monitoring strategies specific to the decision

Any memorandum or other communication transmitting the final decision should be from the primary decisionmaker to the Director of the Office of Nuclear Reactor Regulation (or another appropriate addressee determined by the management lead). The documentation of decisions made using LIC-504 should be entered into the Agencywide Documents Access and Management System.

If the issue and associated analyses warrant, a report may document the process the team followed, the analyses it performed, the integrated assessment of options, the recommendation, and the final decision. Table D-2 is an outline that may be used to help structure such a report.

Communicate the Decision (Step 7 of Figure 4)

The decision and related information should be communicated to the management lead. If the team developed a communication plan, it should ensure that the appropriate stakeholders are informed of the decision. In all cases, the documentation of decisions made using LIC-504 should be entered into the Agencywide Documents Access and Management System.

REFERENCES FOR APPENDIX D

D.1. R.J. Barrett, C.A. Ader, M.E. Mayfield, and S.C. Black, U.S. Nuclear Regulatory Commission, Memorandum to C.J. Paperiello and J.E. Dyer, U.S. Nuclear Regulatory Commission, "Closeout of Davis-Besse Lessons Learned Task Force Recommendation 3.3.7(3)," May 7, 2005 (ADAMS Accession No. ML051380060 and No. ML051380108).

D.2. Management Directive 10.158, "NRC Non-Concurrence Process," U.S. Nuclear Regulatory Commission, March 14, 2014 (ADAMS Accession No. ML18073A296).

D.3: NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk Informed Decision Making," Vol. 1, "Main Report," U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525).

D.4: GAO-04-415, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," U.S. General Accounting Office, May 5, 2004.

Table D-2 Sample Report Format To Document LIC-504 Decision Process

EXECUTIVE SUMMARY

DESCRIPTION OF ISSUE

Background
Characterization of Issue
Detailed Description of Issue

OPTIONS CONSIDERED

EVALUATION AND ASSESSMENT OF OPTIONS

Risk-Informed Evaluations
Integrated Assessment of Options

RECOMMENDATION

FINAL DECISION

PERFORMANCE MONITORING STRATEGIES (IF APPLICABLE)

ATTACHMENTS

Sample list:

- Table B-1, LIC-504 Process Initiation
- communications plan
- Table C-1, Decision Options
- Table D-1, Assessment of Decision Options
- communication to decisionmaker (document, slides, briefing materials)
- detailed analysis files or references to those analyses

Appendix E

Risk-Informed Evaluation Worksheet

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process for Emergent Issues

The U.S. Nuclear Regulatory Commission (NRC) uses a risk-informed evaluation to assess the emergent issue (Step 1 of Figure 4) and each option (Step 3 of Figure 4) identified during the LIC-504 process. The NRC structured this worksheet to parallel the five principles of risk-informed decisionmaking given in Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," issued January 2018 (Ref. E.1), and to address the following:

- meets current regulations
- is consistent with the defense-in-depth philosophy
- maintains sufficient safety margins
- seeks to keep increases in risk small
- uses performance measurement strategies to monitor change

This worksheet is a template of the analysis format to aid the analyst in considering the five principles.

WORKSHEET IDENTIFICATION/COVER SHEET

Summary Description of Issue:

Option #: _____

Option Description:

Analysts: Date:

ANALYSIS TEMPLATE AND GUIDANCE

1. BACKGROUND

- Document the boundary conditions.
- Include assessment (or judgment) of the degree of conservatism in the regulatory analysis of the emergent issue or condition.

2. ASSESSMENT AGAINST THE FIVE KEY PRINCIPLES

For each analysis performed, document the technical adequacy of the methods and information or data used. For all analyses (both risk assessments and traditional engineering approaches), it is important to convey to the decisionmaker the analyst's degree of confidence in the analysis, as well as any assumptions and limitations.

2.1 Compliance with Regulations

The analyst should identify which, if any, regulations are potentially compromised by the issue. The analyst should also identify how the issue may impact licensees' licensing and design basis. The plant's licensing basis could include technical specifications, license conditions, or a final safety analysis report. Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," dated January 7, 2004 (Ref. E.21), provides useful information for this part of the assessment. For purposes of documentation, it is important to summarize the analysis performed to assess whether the regulations are met. The documentation should state uncertainties and conservatism and any key assumptions used to conclude whether a compliance issue exists.

If the staff has entered LIC-504 to risk inform options for which higher tier procedures exist (e.g., potential noncompliance issues), the range of options considered for evaluation should carefully consider the guidance provided in the higher tier procedures.

2.2 Defense in Depth

The assumption is that, at least before the condition or issue arose, the plant met the requirements for adequate defense in depth (i.e., the LIC-504 analysis should not assess whether the plant as-built and as-designed meets defense-in-depth requirements). Section 2.1.1 of Revision 3 to Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," issued January 18, 2019, provides the U.S. Nuclear Regulatory Commission's (NRC's) views on defense in depth as they relate to proposed changes to the licensing basis. According to RG 1.174, there are seven considerations in assessing defense in depth:

(1) Preserve a reasonable balance among the layers of defense.

(2) Preserve adequate capability of design features without an overreliance on programmatic activities as compensatory measures.

(3) Preserve system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to the system, including considerations of uncertainty.

(4) Preserve adequate defense against potential common-cause failures.

(5) Maintain multiple fission product barriers.

(6) Preserve sufficient defense against human errors.

(7) Continue to meet the intent of the plant's design criteria.

Probabilistic risk assessment (PRA) models capture some of these considerations (e.g., system redundancy), while others may reveal themselves (e.g., insufficient depth against human errors) in dominant cutsets generated by a PRA model.

RG 1.174 articulates the above seven considerations primarily from the view point of licensing amendments. Frequently, these amendment requests may be seeking permanent changes to a facility. Conversely, emerging issues and some options that are considered to address emerging issues may be temporary. The LIC-504 team should consider this difference in purpose. For example, compensatory measures that are unacceptable for a permanent change to a facility may be acceptable as an option to manage and mitigate risks associated with an issue until a permanent solution is found. A shift in the balance among layers of defense that may not have been acceptable in the design of the facility may be acceptable as a solution to an emerging issue if a sound quantitative or qualitative analysis shows that the adverse impact on safety is negligible.

These discussions can be used to evaluate how the issue analyzed under LIC-504 impacts defense in depth. Section 2.1.1.4 in RG 1.174 provides guidance on how to integrate the evaluation of the seven individual considerations treated under defense in depth. The following items can be used to structure discussions on the impact of each of the options on defense in depth:

- Does the option propose actions that can compensate for the degradation of defense in depth?
- Does the option identify a programmatic activity that is proposed as a compensatory measure for the identified issue?
- Does the option identify sources of uncertainty with respect to (1) the assessment of the impact of the degradation of defense in depth and (2) either the compensatory measures or monitoring approach?
- Does the option list assumptions made to address the uncertainties and how they support the option and assess the confidence level in the option?

Documenting such discussions may be appropriate if the detailed approach is taken.

2.3 Safety Margins

Section 2.1.2 of RG 1.174 provides an NRC interpretation of safety margins. According to RG 1.174, with sufficient safety margins, (1) the codes and standards or their alternatives approved for use by the NRC are met, and (2) safety analysis acceptance criteria in the licensing

basis (e.g., supporting analyses for the final safety analysis report) are met or proposed revisions provide sufficient margins to account for uncertainty in the analysis and data.

This description of safety margin in RG 1.174 is insufficient for RIDMs such as LIC-504 in that it does not provide the relevance of failure points. Therefore, when treating safety margin in the context of risk assessment, the analyst should consider the failure point in addition to codes and standards and safety analysis acceptance criteria. Figure 6-2 of the "Task Group on Safety Margins Action Plan" (Ref. E.3), a report developed by the Nuclear Energy Agency [NEA] Task Group on Safety Margins Action Plan, depicts safety margin and how it should be considered in the context of risk assessment. Section 4 of the NEA report provides more detail. Additionally, an assessment of potential cliff-edge effect resulting from the emergent condition may help focus decisions. In 2018, the International Atomic Energy Agency, in its "Terminology Used in Nuclear Safety and Radiation Protection," defined a cliff-edge effect as an instance of severely abnormal conditions caused by an abrupt transition from one status of the facility to another following a small *deviation* in a parameter or a small variation in an input value (Ref. E.6). Extreme flooding scenarios and available physical margin used in the NRC's post Fukushima work used in previous LIC-504 assessments serve as an illustrative example of a cliff edge assessment. Another example may involve postaccident combustible gas sources, if the identified degraded condition involves increased postaccident combustible gas that exceeds detonation limits that may fail the reactor containment barrier.

The definition of safety margin in RG 1.174 should be applied to treatment of emerging issues, considering the difference in the purposes of LIC-504 compared to the purpose of RG 1.174, which is to review license amendment requests. To that extent, the NEA report provides additional insights. For example, in determining whether an immediate regulatory action should be taken to order a plant shutdown, consider the plantwide safety margin as reflected in the safety margin of core-damage sequences (i.e., significant degradation of the safety margin of a single component should not automatically lead one to conclude that an order should be issued to shut down a plant). However, a technical specification may prompt a plant to follow such an action, in which case LIC-504 should not be used to obviate that need.

If the PRA model accurately capture the degraded conditions' affect on the failure probabilities as opposed to using conservative assumptions (assuming that the component failed with a probability of 1.0 due to the degradation), then the model may be used effectively evaluate the plantwide impact on the safety margin resulting from the emerging issue.

2.4 Risk Assessment

The purpose of the risk assessment is to provide any available risk insights to the decisionmaker. Not all issues or options are amenable, or require analysis using a PRA model or other quantitative risk assessment. The risk assessment may use any number of techniques or methods, including, but not limited to, quantitative or qualitative bounding analyses, fault-tree/event tree models, likelihood/consequence estimates, initiating event impact assessment, and event sequence analysis. When emergent issues involve plant conditions that the PRA model cannot readily analyze, the analyst should try to determine risk insights germane to the issue or option being evaluated and document these, along with estimates of the uncertainties, to facilitate a decision that is risk-informed to the extent practicable. Engineering judgment should be used to properly characterize the risk insights.

The acceptance guidelines in RG 1.174 and RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decision-Making: Technical Specifications, issued May 2011 (Ref. E.4), may not apply in

cases where core damage frequency (CDF) and large early release frequency (LERF) cannot be estimated. An example would be the degradation of a pressure boundary because of an active process. It would not make sense to try to calculate an increased loss-of-coolant accident (LOCA) frequency for this case. Rather, it may make sense to calculate the probability that a LOCA will occur in the time period of interest. Although numerical guidelines have not been developed for all of the following, the analyst should consider metrics that may be appropriate for a given issue or option, including to develop risk-informed insights:

- CDF and change in CDF (RG 1.174)
- LERF and change in LERF (RG 1.174)
- incremental conditional core damage probability (ICCDP) and incremental conditional large early release probability (CLERF) (RG 1.177)
- large release frequency (LRF) or change in large release frequency (ΔLRF)
- core damage probability (CDP) or large early release probability (LERP)
- conditional core damage probability (CCDP) or conditional large early release probability (CLERP).
- impact on initiating event frequency
- impact on containment bypass scenarios or conditional containment failure probability
- impact on dose to the public (i.e., PRA level 3 considerations)
- quantitative health objectives of the NRC's "Safety Goals for the Operation of Nuclear Power Plants," dated August 21, 1986 (Ref. E.5)
- qualitative health objectives of NRC Safety Goals (Ref. E.5)

2.4.1 Structured Risk Assessment

The following items will enable a structured risk assessment:

- Is this issue amenable to the calculation of risk?
- Describe the model used for the assessment of risk.
  - Does a risk model of sufficient technical adequacy exist that can be used for this analysis?
  - Can a quantitative assessment of an appropriate risk metric (not necessarily CDF/LERF) be performed using risk concepts and methodologies other than a PRA?
  - If a risk model was created specifically for this analysis, describe it and justify its basis using NRC-approved methods.

Note: Available risk models include NRC models such as simplified plant analysis risk or available licensee models. If the licensee's results are used, it must be determined that the model is technically adequate for this evaluation.

- How is the impact of the issue characterized for input to the risk evaluation? *Examples include (1) increased initiating event frequency, (2) increased likelihood of an event over some time period, (3) the actual unavailability of a structure, system, or component, and (4) a possibility of failure under certain conditions.*

- Given this characterization, what risk assessment results can be generated to provide insights for the decisionmaker? *Note: For examples (1) and (3) in the bullet above, it may be possible to calculate CDF or LERF metrics, but probably not for (2) and (4). If the risk assessment results include an increased likelihood of some event over a time period of interest (example (2)), provide the qualitative insights as to which scenarios are affected and an assessment of the CCDP. For example (4), provide the scenarios and a conditional CDF.*

- Are issue-specific data and other input available for use in the risk model? *Note: Plant-specific data may be required in some cases. If "industry-averaged" data are used, justify why this is sufficient.*

- Are there qualitative arguments or analyses that can provide risk insights relating to the application? For example, can the relative direction and magnitude of a change in initiating event frequency, mitigation system reliability, or defense in depth be estimated qualitatively (e.g., small decrease in reliability of a mitigating system)? Discuss the uncertainty associated with such judgment.

  Note: The goal here is to identify to the decisionmaker the potential impacts of the issue or option on risk. The absence of quantitative information should not preclude the analysts from providing and documenting any risk insights developed.

2.4.2 General Scope of Risk Assessment/Probabilistic Risk Assessment

The analyst needs to determine if he or she has considered all sources of risk that may be significant and relevant to the issue or the option being evaluated. The scope of the risk assessment will vary depending on the issue or option. Determine the scope of the risk assessment, including any PRA models, considering the guidance below.

- Does the issue impact the availability and performance of structures, systems, and components, or potential effects on or from human actions, needed to mitigate an external hazard? Does the issue affect the structural response of the plant, given an external hazard? Does the issue limit the impact of an external hazard? *Note: If the answer to any of the questions is "yes," then the risk analysis should also consider the risk from external initiating events.*

- Does the issue introduce new initiating events or change the frequencies of existing events during the low-power and shutdown modes of operation? Does the issue affect the reliability or availability of equipment used for shutdown operations? Does the issue affect the ability of the operator to respond to shutdown events? Does the issue involve potential loss of coolant inventory during shutdown operations? Does the issue affect

long-term residual heat removal? *Note: If the answer to any of the questions is "yes," then the risk analysis should also consider risk from the low-power and shutdown modes of operation.*

- Does the issue involve mechanisms that could lead to bypass of the containment during an accident (e.g., steam generator tube rupture or interfacing system LOCAs)? Does the issue involve mechanisms that could cause failure of containment isolation? Does the issue impact containment systems (including hydrogen igniters) or systems needed to mitigate the release of radioactive material in the short term? Does the issue affect depressurization of the reactor coolant system? *Note: If the answer to any of the questions is "yes," then the risk analysis should also consider LERF as a risk metric.*

- Does the issue impact containment systems or systems needed to mitigate the release of radioactive material in the longer term? Does the issue impact emergency plan implementation? Does the issue affect equipment qualification to the point where it affects timing of equipment failure relative to containment failure? Does the issue affect the core debris path to the sump or the suppression pool or to other portions of the containment?

  Note: If the answer to any of the questions is "yes," then the risk analysis should also consider the large late release as a risk metric. This could be done in a qualitative sense or as part of a PRA model.

2.4.3 Documentation of the Risk Assessment

Caution: The analyst needs to consider how a given option changes the various aspects of the risk assessment performed for the "base case" in Step 1. The analyst should use the risk assessment guidance above when considering the option and document any differences from the base case.

Document the risk evaluation results as follows:

- Identify the risk metrics and acceptance guidance used.

- How does the PRA model represent the effect of the condition?

- Does the risk assessment include the effect of changes made, compensatory measures, or performance monitoring? If so, describe how the analysis includes this effect.

- Consider uncertainty in the risk assessment using the guidance in RG 1.174. NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," issued August 2010, contains additional information on treatment of uncertainties in PRAs. Identify sources of uncertainty that affect the analysis:

  – in the representation of the impact of the condition (how the PRA model changed)
  – in the representation of compensatory measures or monitoring
  – in the base PRA model

- Does the analysis use NRC-approved methods?
- Assess the impact of those uncertainties on the conclusions of the risk assessment.
- Document any key or influential assumptions.
- Document the technical adequacy of risk methods and models used in the assessment.

2.5 Performance Measurement

The fifth key principle of risk-informed regulation, as given in RG 1.174, is that the impact of a proposed change should be monitored using performance measurement strategies. To decide what action the NRC should take in response to an emergent issue, the staff should examine whether the licensees' the performance monitoring strategies are adequate to discover any adverse, unintended consequences. To that extent, Title 10 of the *Code of Federal Regulations* (10 CFR) 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," includes requirements related to monitoring the effectiveness of plant maintenance.

The LIC-504 team can use the following items to structure the discussions of the impact of each of the options on performance monitoring:

- What are the viable means to measure performance and performance monitoring?
- What are the assumptions related to implementing these strategies or measures? (Monitoring may be initiated for a number of reasons, but typically, it provides a feedback loop and validates the assumptions made to support the decision. Different decision options may rely on different aspects of performance monitoring).
- How does monitoring achieve its purpose in a timely manner? (For monitoring to be effective, there must be clear performance criteria, the metric should be amenable to measurement, and it must be sensitive enough to provide sufficient margin).

Documenting parts of such discussions may be appropriate if the team used the detailed approach. For identified performance monitoring strategies, discuss the intent (including how they will provide confidence that the results and assumptions of the underlying engineering analyses or other evaluations remain valid).

REFERENCES FOR APPENDIX E

E.1. 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," U.S. Nuclear Regulatory Commission, January 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17317A256)

E.2. NRR Office Instruction LIC-100, Revision 1, "Control of Licensing Bases for Operating Reactors," U.S. Nuclear Regulatory Commission, January 7, 2004 (ADAMS Accession No. ML072000067).

E.3. NEA/CSNI/R(2007)9, Task Group on Safety Margins Action Plan (SMAP) Safety Margins Action Plan—Final Report, July 9, 2007, Nuclear Energy Agency.

E.4 Regulatory Guide 1.177, Revision 1, “An Approach for Plant-Specific, Risk-Informed Decision-Making: Technical Specifications,” U.S. Nuclear Regulatory Commission, May 2011 (ADAMS Accession No. ML100910008).

E.5 Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Republication; 51 *Federal Register* 30028, August 21, 1986.

E.6 IAEA Safety Glossary, “Terminology Used in Nuclear Safety and Radiation Protection,” 2018 Edition, International Atomic Energy Agency.

E.7 NUREG 1855, Revision 1, “Guidance on the Treatment of Uncertainties Associated with PRAs in Risk Informed Decision Making,” Vol. 1, “Main Report,” U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525).

E.8 Title 10, “Energy, “ Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” Section 50.65, “Requirements for Monitoring the Maintenance Effectiveness at Nuclear Power Plants.”

Appendix F

Reaching Consensus on a Recommendation

Office Instruction LIC-504
Integrated Risk-Informed Decisionmaking Process for Emergent Issues

Unless there are differences of opinion among LIC-504 team members, use of this appendix is unnecessary for the simplified approach and issues of very low safety significance.

This appendix is intended to assist the risk-management team in reaching a consensus during Step 5 (Figure 4) of the process. In that step, the technical staff involved with the analysis will summarize the results for each decision option. The principal analysts in each discipline (e.g., probabilistic risk assessment (PRA), engineering, licensing) will participate in the integration process. The goal of this step is to reach an agreement on a recommendation for the decisionmakers. This group (the integration team) will work to achieve consensus through the following process:

- Summarize the results of individual assessments and present to the group.

- Discuss the results and evaluations of individual assessments under the leadership of a team leader chosen for his or her facilitation skills by the lead organization Branch Chief. (The team leader must facilitate the sharing of information and deliberation.) It is critical during this discussion to raise issues, ask questions, and raise and address concerns about risk information, data sources, and other related subjects. The group discussion may identify the need for additional analyses, reframing of the issue, the involvement of additional staff, or other issues.

- Decide on a decision option to recommend to decisionmakers. As part of these deliberations, the following questions may be considered for each input to the decision to enhance the quality of the decision:

  - Do the results of the assessment support the option?
  - Is the appropriate regulatory principle met?
  - What is the basis for this conclusion?
  - Are the analysis tools and supporting data technically adequate?
    - If the tools are not adequate, describe the inadequacy and potential impacts on the results.
    - If the supporting data are inadequate, describe the data limitations and potential impacts on the results.
  - Is the conclusion clear and unambiguous?
    - What are the uncertainties that affect this assessment?
    - What confidence do we have in the results or conclusion?
    - What is the significance of the results?

- In the case of an individual assessment not supporting the option, do the results of the other assessments have more weight?
    - How important is this specific assessment to this particular option?
- With the help of the team leader, attempt to reach consensus on the driving factors or considerations. Consensus is defined as agreement among the integration group members on which decision option is considered "preferred" for recommending to the decisionmakers.

If the integration team cannot achieve consensus, options include the following:

- The dissenters can agree to let the group move on, comparable to abstaining in voting. This minority opinion will be communicated to the decisionmaker along with the recommended decision option(s).
- The team can repeat the process and conduct additional analysis.
- If the disagreement cannot be reconciled by additional information or analysis, the team can seek management guidance to review the analysis and make a decision based on available analyses.

Dissenters have the option to enter the U.S. Nuclear Regulatory Commission's nonconcurrence process described in Management Directive 10.158, "NRC Non-Concurrence Process," dated March 14, 2014 (Ref. F.1).

RERERENCE FOR APPENDIX F

F.1. Management Directive 10.158, "NRC Non-Concurrence Process," U.S. Nuclear Regulatory Commission, March 14, 2014 (Agencywide Documents Access and Management System Accession No. ML18073A296).