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

# *NRR OFFICE INSTRUCTION*

## Change Notice

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|---|---|
| **Office Instruction No.:** | LIC-504, Revision 4 |
| **Office Instruction Title:** | Integrated Risk-Informed Decision-Making Process for Emergent Issues |
| **Effective Date:** | June 2, 2014 |
| **Approved By:** | Jennifer Uhle |
| **Date Approved:** | May 30, 2014 |
| **Primary Contacts:** | Steven A. Laur<br>(301) 415-2889<br>steven.laur@nrc.gov |
| **Responsible Organization:** | NRR/DRA |

**Summary of Changes:** This is Revision 4 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. This revision 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.

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| **Training:** | Self study |
| **ADAMS Accession No.:** | ML14035A143 |

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

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**NRR OFFICE INSTRUCTION**
**LIC-504, Revision 4**

**Integrated Risk-Informed Decision-Making Process for Emergent Issues**

## 1. POLICY

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to employ the strategies delineated in the Strategic Plan (Ref. 1) to meet the agency's performance goals. In particular, we will undertake the following:

- Develop, maintain, implement, and improve licensing and regulatory programs to ensure the adequate protection of public health and safety
- Oversee the safe and secure operation of existing facilities and uses of nuclear material
- Use sound science and state-of-the-art methods to establish, where appropriate, risk-informed and performance-based regulations
- Promote awareness of the importance of a strong safety culture and individual accountability of those engaged in regulated activities
- Use domestic and international operating experience to inform decision-making
- Oversee licensee safety performance through inspections, investigations, enforcement, and performance assessment activities

In addition, we will support the efforts of other offices to employ these strategies.

## 2. OBJECTIVES

The objective of this office instruction is to outline a process for the development and documentation of risk-informed decisions. This process has been created for risk-informed decision-making regarding emergent issues relevant to nuclear power plants. However, the basic steps can be followed to address issue in any area regulated by the NRC.

This process is not intended to replace existing risk-informed decision-making processes (e.g., Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," (Ref. 2); Management Directive (MD) 8.3, "NRC Incident Investigation Program," (Ref. 3); and NRR Office Instruction LIC-401, "NRR Reactor Operating Experience Program," (Ref. 4)). Therefore, the guidance in this document, in particular the templates in Appendices B and C, may be used to supplement existing risk-informed processes if desired, but the general intent is that established processes applicable to the emergent issue would be used instead of LIC-504 when such processes apply.

## 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," issued May 2004 (Ref. 5), 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 and that could occur at nuclear power plants in the future. With regard to the areas of risk evaluation, communication, and the decision-making process for determining if plant shutdown is warranted, GAO made the following 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 U.S. Nuclear Regulatory Commission's (NRC's) use of probabilistic risk assessment (PRA) estimates in decision-making by (1) ensuring that the risk estimates, uncertainties, and assumptions made in developing the estimates are fully defined, documented, and communicated to NRC decision-makers, and (2) providing guidance to decision-makers 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 has been developed to address these recommendations. However, it is recognized that the various inputs to a given decision can be very different in nature, thus making it difficult to develop a formal process for combining them. Therefore, the LIC-504 process focuses on documenting those inputs so that their contribution to the resulting decision can be clearly understood by the decision-maker. LIC-504 also focuses on documenting the decision so that the driving factors are identified and suitably qualified to address uncertainties.

## 4. BASIC REQUIREMENTS

Caution: If at any time it is determined that an immediate shutdown of a plant is required, NRR Office Instruction LIC-106, "Issuance of Safety Orders" (Ref. 6), or the NRC Enforcement Manual process (Ref. 7) should be entered. If LIC-504 has already been implemented when it is determined that an immediate plant shutdown is necessary, the LIC-504 process should not be permitted to interfere with taking necessary and timely action. LIC-504 may be suspended or curtailed at that time by cognizant management.

### 4.1 Risk-Informed Approach to Decision-Making

As defined in the Staff Requirements Memorandum to SECY-98-0144, "White Paper on Risk-Informed and Performance-Based Regulation" (Ref. 8), a risk-informed approach to regulatory decision-making represents a philosophy whereby risk insights are considered together 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. For nuclear power reactors, there are five key principles of risk-informed regulation that serve as the foundation of sound risk-informed decision-making. These key principles are:

- Compliance with existing regulations
- Consistency with the defense-in-depth philosophy
- Maintenance of adequate safety margins
- Demonstration of acceptable levels of risk
- Implementation of defined performance measurement strategies.

Various risk-informed processes generally differ in the manner by which they demonstrate that the key principles are satisfied. When LIC-504 is employed, the five key principles are used to differentiate among various options for resolving the issue. Use of the key principles in this way is contrasted with their use in RG 1.174 (Ref. 2) in the following paragraphs.

Compliance with existing regulations (unless an exemption is sought) is fairly straightforward when a licensee requests a change to the licensing basis of its facility – the subject of RG 1.174. However, 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.

Note that there is a presumption of adequate protection of public health and safety afforded by compliance with NRC's regulations. New information regarding an unforeseen or substantially more likely hazard could raise "special circumstances" that could rebut this presumption. Appendix D of Standard Review Plan Section 19.2 (Ref. 9) provides additional information regarding "special circumstances."

Consistency with the defense-in-depth philosophy in 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. For some issues, defense-in-depth may be at the heart of the issue – that is, the new information may reveal insufficient defense-in-depth for the existing facility. Appendix D of this Office Instruction provides questions to assist in determining the extent to which defense-in-depth is maintained for the various options being considered.

Maintenance of adequate safety margins in RG 1.174 includes compliance with codes and standards and meeting the safety analysis acceptance criteria in a plant's licensing basis. The LIC-504 approach for this key principle is no different. Appendix D of this Office Instruction provides questions to assist in evaluating how well each proposed option for addressing an emergent issue maintains safety margins.

Demonstration of acceptable levels of risk in 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 NRC must take prompt action 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 in choosing from among the options. Note that a quantitative risk assessment may prove difficult to obtain for many emergent issues. Qualitative risk assessments may be employed as appropriate.

Implementation of defined performance measurement strategies in RG 1.174 means to ensure monitoring is put in place so that (1) the desired outcomes of the change are obtained and (2) unintended adverse consequences of the change can be detected in time to take corrective action. This is the same for LIC-504. The decision regarding an emergent issue may apply for a finite time period (e.g., until a licensee can effect a permanent repair), so that this Office Instruction includes compensatory measures within the scope of this key principle. Appendix D includes guidance for performance monitoring and compensatory measures.

Section 4.1 describes the entry conditions for LIC-504, including guidance on selecting the standard or detailed approach. Section 4.2 provides an overview of the risk-informed decision-making process, which is applicable to either approach. Appendix B provides guidance on the standard approach to risk-informed decision-making. Appendix C provides guidance on the detailed approach to risk-informed decision-making.

### 4.2 Entering LIC-504

LIC-504 applies when (1) new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as identification of an issue that may substantially increases risk; and, (2) no other NRC process exists for addressing the issue. This process is intended for making and documenting risk-

informed decisions regarding what action the NRC should take in response to a potentially significant, emergent issue at a US nuclear power plant.

The resources to follow the process described in this office instruction in its entirety could be significant, even for the standard approach. For this reason, this office instruction is intended to be used in cases where the decision is not obvious or the options are not readily identified and evaluated. For routine decisions or decisions for which another NRC procedure or process entirely addresses how to resolve and document resolution of the issue, LIC-504 may not be appropriate. On the other hand, LIC-504 may be used to supplement other processes, by providing a decision-making structure and formal documentation. The items to be considered, report formats, and content suggestions provided in this office instruction should be taken as guidance rather than as procedural requirements. In all cases where LIC-504 is implemented, the level of analysis and documentation should be commensurate with the significance of the emergent issue and the corresponding decision to be made.

Once it has been decided to begin the LIC-504 process, the “standard approach” set forth in Appendix B should be used. As the team gains familiarity with the issue and develops options, it may determine that the “detailed approach” set forth in Appendix C is appropriate. The detailed approach may be indicated if the issue is of such complexity that a very detailed assessment of most or all of the five key principles of risk-informed decision-making is warranted. Section 4.2.4 discusses factors to consider when determining whether to progress to the detailed approach.

Figure 1 provides a flow chart as an aid in determining whether LIC-504 should be entered.

LIC-504 is not intended for routine decisions or decisions for which another NRC procedure or process entirely addresses how to resolve and document resolution of the issue. Examples include LIC-106, “Issuance of Safety Orders,” Management Directive 8.3, “NRC Incident Investigation Program,” and Management Directive MD 6.4, “Generic Issues Program.” LIC-504 may not be used to replace an applicable NRC procedure or process.

The box in Figure 1 that asks whether the issue comes under another NRC process provides examples of some issue types for which there are already processes in place. That list is not comprehensive and should be taken as only providing examples. Also, the flow chart provides general guidance, but should not be taken as prescriptive.

Even though another process may apply and LIC-504 is exited, this procedure includes useful guidance on how to apply the five key principles of risk-informed decision-making. Therefore, division management may direct that guidance contained in the appendices of LIC-504 be used to structure decision-making under the other process.

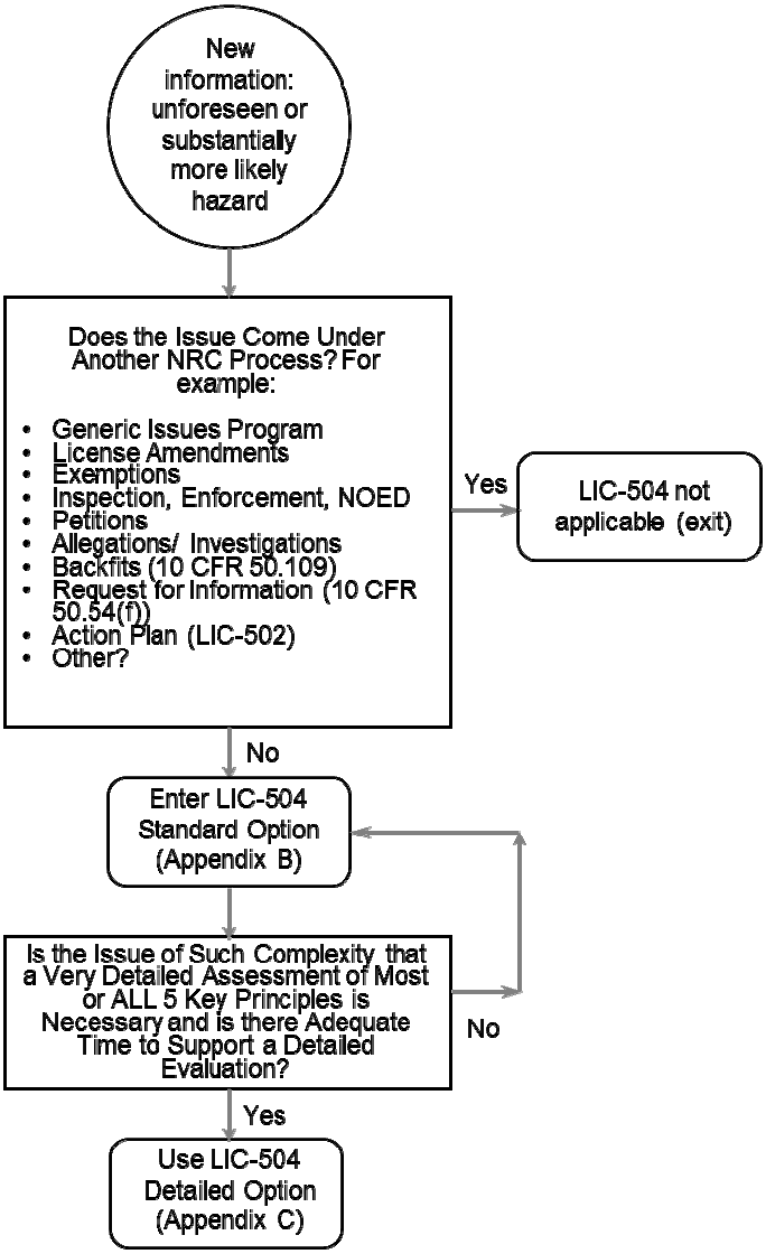


**FIGURE 1: ENTERING LIC-504**

### 4.2.1 Is Immediate Regulatory Action Required?

The first GAO recommendation (Section 3 above) 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 (Refs. 6 or 7, respectively) should be entered.

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 are guidelines, any of which may be used to question whether additional regulatory action is required to place or maintain the plant in a safe condition:

- Defense-in-depth 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).
- There is significant loss of safety margin (e.g., the calculated ASME code structural factors for a component are equal to or less than 1).
- The risk impact from internal or external events is high, as determined using risk metrics such as the following:[1]
    - Core damage frequency (CDF) or conditional core damage frequency (CCDF) is high (e.g., greater than or on the order of $1x10^{-3}$/yr)
    - Large early release frequency (LERF) or conditional large early release frequency (CLERF) is high (e.g., greater than or on the order of $1x10^{-4}$/yr)
    - Incremental conditional core damage probability (ICCDP) is high (e.g., greater than or on the order of $5x10^{-5}$)
    - Incremental conditional large early release probability (ICLERP) is high (e.g., greater than or on the order of $5x10^{-6}$)

Insufficient or inadequate information will necessitate making conservative assessments as to whether the criteria listed above are met. Uncertainties should be factored in when making the assessments.

### 4.2.2 Is the Issue Clearly of Low Safety Significance?

Issues that are clearly of low safety significance do not need to be assessed using this instruction. Therefore, if at any stage it is clearly concluded that the safety concern can be considered of low significance, the process can be exited. In this case, it should be clear that the risk impact is very small (e.g., $\Delta CCDF < 1x10^{-7}$ per reactor year), and there is minimal degradation of defense-in-depth or safety margin. All five key principles of risk-informed regulation as defined in RG 1.174 should be considered to the extent warranted. The information and/or analyses used to reach this conclusion should be documented and communicated. In such cases, the standard approach (Appendix B), or portions thereof, may be used as desired.

[1]The conditional core damage frequency (large early release frequency) is the CDF (LERF) evaluated with the impact of the issue taken into account: it represents the height of the risk spike. The ICCDP (ICLERP) is the area under the risk spike above the average risk level corresponding to the duration of the impact of the issue and represents the contribution of that occurrence of the issue to risk.

### 4.2.3 Need for Communication Plan

For some emergent issues, a formal communication plan may be needed. A communication plan is called for in 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 a large number of stakeholders.

For additional information, refer to the internal NRC Communication Plan Guidance at:

http://www.internal.nrc.gov/communications/plans/guidance.html

A communication plan does not have to be developed for every NRC activity, even if the detailed approach in LIC-504 is warranted. For some activities, a different type of communications tool may be appropriate. If the user is unsure as to what type of communication tool is appropriate, contact the office/region communications specialist or check information on communication tools at:

http://www.internal.nrc.gov/communications/tools/tools-with-teeth.pdf

### 4.2.4 Progressing to the Detailed Approach

Many issues are straightforward, the options fairly obvious, and the analysis involves only one or a couple of factors that would differentiate the options. Other issues are complex, require substantial effort to understand and analyze, or have important impacts on the various stakeholders. Both the standard and detailed approaches use the steps of the risk-informed decision-making process. As stated in the introduction to this section, the standard approach should be used whenever LIC-504 is entered. The team can progress to the detailed approach if warranted as the team becomes further acquainted with the emergent issue.

Some factors that may lead to selection of the detailed approach include the following:

Need for Highly Deliberative Decision Process

Decisions that require a highly deliberative decision process, involve multiple technical disciplines, involve large uncertainty, or may have unintended consequences are candidates for the detailed approach. The detailed approach of LIC-504 may be applicable for issues that are highly complex. Such issues may have generic implications for licensees or may be broad-reaching in their impact on safety.

Issues that are highly visibly or controversial may also benefit from application of the detailed approach of LIC-504. If an issue is of interest to multiple stakeholders or has the potential to generate public concern or outrage, the documentation of the decision may benefit from the formality and rigor of the detailed approach.

For many issues, however, it may be relatively straightforward to develop options, select the most appropriate option, and document the decision, without the burden associated with implementation of the detailed approach. For such issues, the standard approach would be indicated.

Need for Structured Assessment of Risk, Defense-in-Depth, Safety Margins

The detailed approach is useful when a structured assessment of the five key principles of risk-informed decision-making (see Section 4.1 of this Office Instruction) is needed. On the other hand, when only one or two factors serve to differentiate among options to address an issue, the standard approach may be more appropriate. Note that, for either the standard or detailed approach, the differentiating factor or factors need not be from among the five key principles.

Appendix B of this Office Instruction should be used for those issues where the LIC-504 standard approach is selected. Appendix C should be used when the detailed approach is chosen. 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 may be used or modified as desired.

### 4.3 The Risk-Informed Decision-Making Process

Figure 2 outlines the process to be followed for risk-informed decision-making. This process includes seven steps, as well as the additional important activities of information gathering and technical analysis that are inputs to multiple steps. An overview of these steps is provided below. Detailed guidance on each step is presented in Appendix B for the standard approach and in Appendix C for the detailed approach.

The LIC-504 process is expected to be an iterative one. 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 re-visiting these steps until a recommendation can be made to the decision-maker. 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 common to other risk-informed decision-making processes (e.g., Ref. 2). Information is gathered and technical analyses performed at this point in the process. What makes this decision process “risk-informed” is the use of the five key principles discussed in Section 4.1, above. Steps 1 – 3 will likely be

performed in an iterative fashion, as the technical staff identifies additional information necessary to support the analyses.

Step 4 is also part of the risk-informed decision-making process, e.g., the integrated decision-making step in RG 1.174. However, RG 1.174 and related documents only briefly discuss this important step. Therefore, this office instruction provides additional guidance in Appendices B and C for integrating the various factors that will influence the ultimate decision on what action should be taken to address the emergent issue. In comparing the various options intended to address the emergent issue, the team should again use the five key principles from Section 4.1 to determine which option best addresses the issue.

Appendix E 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 NRC's non-concurrence process as set forth in Management Directive 10.158, "NRC Non-Concurrence Process" (Ref. 10). The LIC-504 process can proceed in parallel with the non-concurrence process. Cognizant NRC management should decide whether to continue the LIC-504 assessment on the originally planned schedule or to delay the assessment pending completion of the non-concurrence process. In any event, the decision authority should be fully informed of any non-concurrences relating to the issue under consideration in addition to the recommendation being made by the LIC-504 team.

Step 5 is to communicate the team's recommendations to the decision authority. The purpose of this step is to provide the decision-makers with the information they need to make a properly informed decision. Typically, the decision-maker will need a brief summary and characterization of the issue, the options considered, the recommended option, and the basis for that recommendation. Any recommended performance monitoring strategies should also be presented at this briefing.

Step 6 is to document the decision. A memorandum will be used to document the final decision. The decision maker's rational for the chosen approach for addressing the emergent issue should be discussed. Concurrence should be obtained from all the affected technical branches and project manager branches. 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 the Agency-wide Documents Access and Management System (ADAMS).

Step 7 is to communicate the decision to affected and interested parties. If a communication plan was developed, then it will serve to ensure that appropriate stakeholders are informed of the decision. Useful information on communicating risk information may be found in NUREG/BR-0318, "Effective Risk Communication—Guideline for Internal Risk Communication," (Ref. 11) and in NUREG/BR-0308, "Effective Risk Communication—The Nuclear Regulatory Commission's Guideline for External Risk Communication," (Refs. 12 and 13).

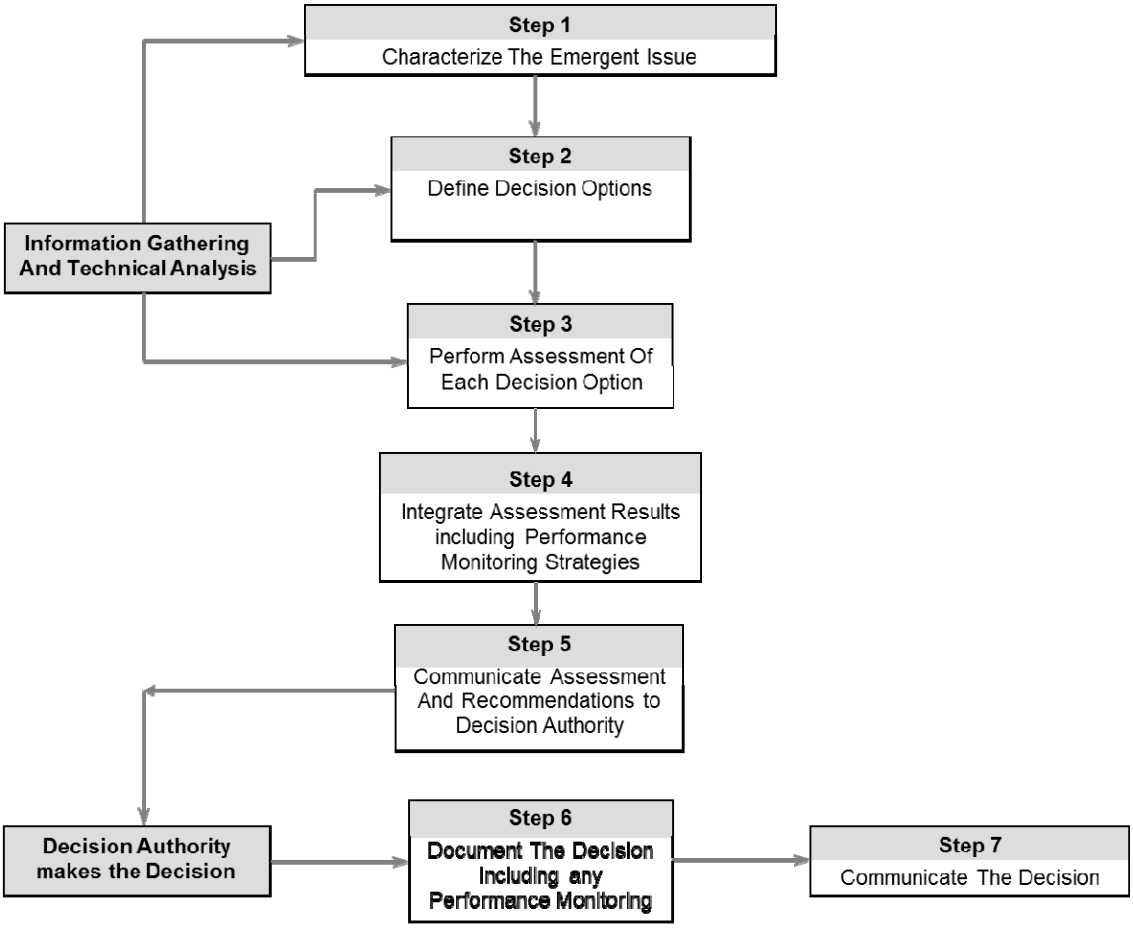


**FIGURE 2: RISK-INFORMED DECISION MAKING PROCESS**

Underlying all steps in the process is the need for documentation. Appendix B and Appendix C provide templates for documenting the decision-making process for the standard and detailed approach, respectively. The resulting report should document the emergent issue, options considered, bases for the recommended option, the individuals involved in the decision-making, 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" (e.g., 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 impacted, 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 decision-makers to be prepared for communication activities during and at the end of this risk-informed process. Placing emphasis on communication during the process will help identify topics that require clarification by the staff and focus attention on ensuring that all

participants share an understanding of the subject, objective, terms, and assumptions at hand; this will encourage discussion and prevent misunderstandings among team members and therefore 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. 11, 12 and 13) emphasize the importance of explicitly addressing communication challenges early in a process.

Final documentation developed as part of this process should be placed in the Agency-wide Documents Access and Management System (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 and Figure 1.

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

Management Lead

The Management Lead is responsible for the identification and use of resources in support of implementation of the LIC-504 process. The Management Lead will work with the Technical Lead and the Responsible Project Manager to maintain process schedule and milestones. The Management Lead will facilitate communication of status, resources 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 to ensure that should information suggest an immediate safety concern that appropriate communications and measures are taken to ensure the safe operation of any affected facility.

Responsible Project Manager

The project manager (PM) responsible for either the affected site or process is responsible for coordinating review and resolution activities. The PM will pull a Technical Assignment Control (TAC) number to ensure fee recovery and support tracking of work activities. Consistent with Management Directive 3.5 and COM-203, the PM will ensure proper documentation of interim and/or final decisions made in meetings. This may require the development of a communication plan and/or action plan. In addition, the PM will support the development and concurrence of the LIC-504 report, and is also responsible for coordination activities with other Offices as well as the

Regions and support of 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, the individual will recommend to the cognizant manager whether it is necessary to use the detailed approach. The technical lead will coordinate the technical review for that issue. The Technical Lead will be responsible to coordinate with the responsible PM, and other Offices, as applicable, to ensure the technical consistency for the issue.

Regional Manager

The decision process for some emergent issues may benefit significantly from information provided by the affected Regional Office. The regional manager responsible for the affected site may be requested by the management lead for the issue to provide specific information regarding plant status and/or operation. These interactions should be coordinated through the responsible project manager for the site. 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 to not adversely affect the inspection staff's ability to perform required inspection activities.

Team Members

All NRR staff members who are assigned as team members for implementing the LIC-504 process should read and understand the process and fully participate in the steps set forth herein. 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) is responsible for performing the coordination functions delineated in the basic requirements section of this office instruction. The primary contact is expected to be the NRR subject matter expert on this office instruction, the associated process, and related issues. The primary contact is responsible for giving day-to-day advice on the office instruction and for monitoring the staff's use of it. The primary contact interfaces with the staff, management, work planning center, 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 Branch Chief of the Probabilistic Risk Assessment Licensing Branch in the Division of Risk Assessment is the responsible manager for this office instruction and is responsible for developing, implementing, and maintaining this office instruction. 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 to the office instruction. The responsible manager will ensure that any required periodic review is completed and will approve the review by concurring in the required documentation.

## 6. PERFORMANCE MEASURES

The objective of this office instruction is to ensure that risk-informed decision-making activities are coordinated and integrated such that the performance measures identified in the Strategic Plan can be met and NRR resources are used in an efficient and effective manner. No performance measures are specified for this office instruction.

## 7. PRIMARY CONTACT

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steven.laur@nrc.gov

## 8. RESPONSIBLE ORGANIZATION

NRR/DRA

## 9. EFFECTIVE DATE

June 2, 2014

## 10. REFERENCES

1. COMSECY-2011-0017 – Enclosure: NUREG-1614, V5, “Strategic Plan: Fiscal Years 2012-2016,” U.S. Nuclear Regulatory Commission, February 2012 (ADAMS Accession No. ML11322A189)
2. Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 2, U.S. Nuclear Regulatory Commission, Washington, DC, May 2011 (ADAMS Accession No. ML100910006)
3. Management Directive 8.3, “NRC Incident Investigation Program,” U.S. Nuclear Regulatory Commission, March 27, 2001 (ADAMS Accession No. ML031250592)
4. NRR Office Instruction LIC-401, “NRR Reactor Operating Experience Program,” Revision 3, U.S. Nuclear Regulatory Commission, June 3, 2013, (ADAMS Accession No. ML12192A058)

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

7. The NRC Enforcement Manual, Revision 9, U.S. Nuclear Regulatory Commission, September 9, 2013 (ADAMS Accession No. ML102630150)

8. Staff Requirements Memorandum SRM-SECY-98-0144, “White Paper on Risk-Informed and Performance-Based Regulation,” U.S. Nuclear Regulatory Commission, March 1, 1999 (ADAMS Accession No. ML003753601)

9 NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” 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, Washington, DC, June 2007 (ADAMS Accession No. ML071700658)

10. Management Directive 10.158, “NRC Non-Concurrence Process (DRAFT) - Interim Guidance,” U.S. Nuclear Regulatory Commission, December 2012 (ADAMS Accession No. ML12346A077)

11. NUREG/BR-0318, “Effective Risk Communication—Guideline for Internal Risk Communication,” U.S. Nuclear Regulatory Commission, December 31, 2004 (ADAMS Accession No. ML050960339)

12. NUREG/BR-0308, “Effective Risk Communication—The Nuclear Regulatory Commission’s Guideline for External Risk Communication,” U.S. Nuclear Regulatory Commission, February 29, 2004 (ADAMS Accession No. ML040690412)

13. NUREG/BR-0308, Supplement 1 “Effective Risk Communication—The Nuclear Regulatory Commission’s Guideline for External Risk Communication, Quick Reference Guide,” U.S. Nuclear Regulatory Commission, February 29, 2004 (ADAMS Accession No. ML040690441)

14. Regulatory Guide 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” Revision 2, U.S. Nuclear Regulatory Commission, Washington, DC, March 20091 (ADAMS Accession No ML090410014)

15. 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 Nos. ML051380060 and ML051380108).

16. NRR Office Instruction LIC-100, “Control of Licensing Bases for Operating Reactors,” Revision 1, U.S. Nuclear Regulatory Commission, January 7, 2004 (ADAMS Accession No. ML033530249)

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

18. NUREG-1855, ‘‘Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-informed Decision Making,” U.S. Nuclear Regulatory Commission, March 2009 (ADAMS Accession No. ML090970525)

Enclosures:

1. Appendix A, Change History
2. Appendix B, Standard Approach to Risk-Informed Decision-Making
3. Appendix C, Detailed Approach to Risk-Informed Decision-Making
4. Appendix D, Risk-Informed Evaluation Worksheet
5. Appendix E, Reaching Consensus on a Recommendation

## Appendix A

## Change History

## Office Instruction LIC-504
## Integrated Risk-Informed Decision-Making Process for Emergent Issues

| LIC-504 — Change History — Page 1 of 2 | | | |
|---|---|---|---|
| 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 — Page 2 of 2 | | | |
|---|---|---|---|
| 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:<br>• Strategies in the "policy" section updated to match current Strategic Plan<br>• 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.<br>• The discussion regarding communication plans was elevated to a sub-section (4.2.3) and applies to the standard or detailed approach.<br>• Figure 1 was greatly simplified and now provides examples of "other processes" that would result in not entering LIC-504.<br>• 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.<br>• Figure 2 was revised to show the actual decision being made and to refer to "performance monitoring"<br>• The relationship of LIC-504 to the non-concurrence process is discussed<br>• References were updated or added for completeness<br>• Attachments 1 and 2 to Appendix C were re-named Appendix D and E, respectively<br>• Other editorial changes were made to improve readability | Email to all staff | Self-study |

## Appendix B

## Standard Approach to Risk-Informed Decision-Making

### Office Instruction LIC-504
### Integrated Risk-Informed Decision-Making Process for Emergent Issues

Once it has been decided to enter LIC-504, the process starts with the standard approach, as set forth in this Appendix. As the analysis of the emergent issue proceeds, it may be decided that the additional detail provided in Appendix C (the detailed approach) is warranted. The management lead will make the decision regarding whether or not to progress to the detailed approach. The team would continue working towards resolving the issue, but would use the more detailed forms in Appendix C to structure the analysis of the various options.

When the standard approach of LIC-504 is applied to an emergent issue, the following steps are recommended.

### 1 – Initiate the LIC-504 Process

The standard approach does not need a formal meeting to initiate the process. In many cases an individual or small team may suffice to perform the steps shown in Figure 2 for the risk-informed decision-making process. However, some structure may be useful for many issues that warrant the standard approach. The following steps, while optional, provide a degree of structure that management may tailor to the specific issue being considered.

Identify the decision authority – This is the individual who or NRC organization that will make the decision. Depending on the decision, potential decision-makers include Branch Chiefs, Division Directors, the Risk-Informed Licensing Panel, Office Directors/Regional Administrators, or the NRC Executive Director for Operations.

Identify the NRC organizations involved in supporting the decision – Consider the functions/analysts that are needed to conduct the analysis; e.g., the technical area expertise needed.

Name a management lead for the effort – This will normally be a Division Director or Branch Chief in the organization having primary responsibility for resolving the issue. The management lead should:

- 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.
- Determine whether a Communication Plan is necessary. If so, assign a communications lead. This individual should coordinate with the Office of Public Affairs for issues of high

stakeholder interest, as appropriate. (Refer to Section 4.2.3 in the body of this Office Instruction.)

- Set expectations for the team, such as (1) team member participation has a high priority; (2) 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.

**2 – Perform Steps 1 – 4 of the Risk-Informed Decision-Making Process (Figure 2)**

The technical lead (and team, if applicable) performs the first four steps of the risk-informed decision-making process shown on Figure 2 of LIC-504. The results of each step should be captured as working notes, document files, analysis files, and so forth, to aid in documenting the decision in step 5, below (step 6 of Figure 2).

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 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:

- Identifying the structures, systems, and components (SSCs) or operational characteristics affected by the issue (including human actions).
- Describing the nature of the effect on the identified SSCs or operational characteristics.
- Documenting the potential impacts of the issue on safe operation of the plant.
- Identifying the regulations (or other requirements/commitments such as design basis, licensing basis, generic letters) that may be challenged by this issue.

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

Define Decision Options (Step 2)

The purposes of this step are to define the decision-making environment, to develop the decision options, and to describe the decision criteria for evaluating the options.

The decision-making environment includes the key boundary conditions for the assessment, considering the urgency, severity, and expected duration of the issue. Analysis tools and techniques applicable to the issue, including risk analysis methods, should be identified.

Enclosure 2

| 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 | | | |
| | | | |
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| | | | |
| ADAMS Accession No. _____ | | | |

A decision, or set of options to evaluate in the decision-making process, should be developed. For each identified option, the technical lead or team should identify the potential impact on the principles of risk-informed decision-making, to the extent they apply, or other factors that aid the decision process. Decision criteria that will form the basis for acceptability or rejection for each decision option should be selected to facilitate evaluating the options.

Table B-2 provides a convenient format for capturing the options that were considered to address the emergent issue, and the analysis approach, affected principles or factors, and the evaluation criteria. Table B-2 also includes a column to document the evaluation of each option (next step in the process). Even if the table is not filled out, it illustrates the process for documenting the evaluation.

Perform Assessment of Each Decision Option (Step 3)

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

- Compliance with existing regulations
- Consistency with the defense-in-depth philosophy
- Maintenance of adequate safety margins
- Demonstration of acceptable levels of risk
- Implementation of defined performance measurement strategies.

While the factors used in the standard approach may coincide with the five key principles of risk-informed decision-making, there may be issues where 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) relative impact on public confidence among options; and, (4) relative burden to licensees. There is no reason to “force fit” a discussion of non-informative factors into the documentation. Conversely, there may be any number of other factors that are relevant to the decision that should be considered. 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 may be included in Table B-2. Note that this is a simplification in the standard approach compared to the detailed approach in Appendix C, where each option may have an individual evaluation sheet (Table C-3). In the standard approach, this documentation may be combined.

| Table B-2: Decision Options | | | | | |
|---|---|---|---|---|---|
| # | Option[1] | Analysis Approach[2] | Affected Principles or Factors[3] | Criteria used to Evaluate Options[4] | Evaluation[5] |
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Notes:
1. Define each decision option (e.g., shut down plant immediately or shut down in specified time period)
2. What analytical tools are available (e.g., risk analysis tools or engineering models) – may be quantitative or qualitative
3. Identify potential impact on the principles of risk-informed decision-making 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 that is being recommended for implementation.

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. A recommended option must be selected from the acceptable options that have been evaluated. The integration process may be as simple as providing a brief summary of the option or options for addressing the issue and presenting the factor or factors that differentiate the preferred option from alternatives. The “pros and cons” for each option may be one way to justify preferring one option over another.

The comparison of the options and recommending an action to the decision authority can sometimes be a contentious team activity. Appendix E 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 NRC’s non-concurrence process as set forth in Management Directive 10.158, "NRC Non-Concurrence Process" (Ref. 10). The LIC-504 process can proceed in parallel with the non-concurrence process. Cognizant NRC management should decide whether to continue the LIC-504 assessment on the originally planned schedule or to delay the assessment pending completion of the non-concurrence process. In any event, the decision authority should be fully informed of any non-concurrences relating to the issue under consideration in addition to the recommendation being made by the LIC-504 team.

The LIC-504 team should also consider what, if any, performance monitoring strategies should be put in place along with the recommended action. 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.

**3 – Communicate Assessment and Recommendations to the Decision Authority (Step 5 of Figure 2)**

The purpose of this step is to provide the decision-makers with the information they need to make a properly informed decision. Typically, the decision-maker will need information presented in summary format for rapid assessment and ease of understanding the impacts and complexity of an issue. Slides or other briefing media may be used to facilitate a meeting with the decision-maker.

The briefing of the decision-maker should include a brief summary and characterization of the issue, the options considered, the recommended option, and the basis for that recommendation. Any recommended performance monitoring strategies should also be presented at this briefing.

**4 – Decision Authority makes the Decision**

The decision authority, using the information provided in the briefing and any other information he or she deems relevant to the issue, decides what should be done to address the emergent issue. The decision might be to implement the option recommended by the LIC-504, or it may be to implement some other action. The decision could even be to not take any action. The decision authority should also consider any recommended performance monitoring strategies and determine what performance monitoring, if any, should be put in place to monitor whatever action has been 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 that the decision maker be provided with the best information available, including limitations and uncertainties in the technical analyses that support any recommendation, to facilitate good decisions.

The decision authority should communicate his or her basis for the decision, so that basis can be documented (next step). This basis should be fairly detailed when the decision is to adopt some course of 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 GAO report (Ref. 5).

**5 – Document the Decision including Performance Monitoring (Step 6 of Figure 2)**

Once the decision has been made, the staff should document the decision. A memorandum or other communication should be used to document the final decision. The decision maker's rational for the chosen approach for addressing the emergent issue should be discussed. If provisions for performance monitoring were deemed necessary, they should be described in the document as well.

If the issue and associated analyses warrant, a report may be generated to document the process that was followed, the analyses that were performed, the integrated assessment of options, the recommendation, and the final decision. Documentation of the decision should include not only what the decision was, but also any insights provided by the decision-maker.

Table B-4 provides an outline that may be used to help structure a report if one is desired.

**6 – Communicate the Decision (Step 7 of Figure 2)**

The decision and related information should be communicated as appropriate to the issue under consideration. If a communication plan was developed, it should be used to ensure that appropriate stakeholders are informed of the decision. In all cases the documentation of decisions made using LIC-504 should be entered into the Agency-wide Documents Access and Management System (ADAMS).

{LIC-504 Standard Approach Ends}

Table B-4: 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 B-2, if used.)

EVALUATION AND ASSESSMENT OF OPTIONS

(Provide a brief summary of the option or options for addressing the issue. Present the factor or factors that differentiate the preferred option from alternatives. Include "pros and cons" for each option as appropriate. Attach Table B-2 if used.)

RECOMMENDATION

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

FINAL DECISION

PERFORMANCE MONITORING STRATEGIES (IF APPLICABLE)

ATTACHMENTS

As needed

## Appendix C

## Detailed Approach for Risk-Informed Decision-Making

## Office Instruction LIC-504
## Integrated Risk-Informed Decision-Making Process for Emergent Issues

The decision to progress to the detailed approach of this instruction will be made by the Director of the Division with lead responsibility for the issue (or designee), in consultation with appropriate NRR senior management and the Director of the Division of Risk Assessment (DRA). If requested by the Management Lead, the Director of DRA will assign an individual to be the team facilitator for implementing LIC-504. (Typically, this would be the LIC-504 process owner.)

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 set forth in Appendix B. The intent is to build on the work done up to the point that the detailed approach is selected.)

### 1 – Continue the LIC-504 Process

Define Decision Options (Step 2 of Figure 2)

The purposes of this step are to define the decision-making environment, to develop the decision options, and to describe the decision criteria for evaluating the options.

*Environment in which the Decision will be Made* – The team should identify the key boundary conditions for the assessment, considering the urgency, severity, and expected duration of the issue. The team should consider whether the issue is dynamic or static in nature. The team should determine what risk analysis tools are available that are capable of addressing the issue.

*Decision Options* – The team should define options to resolve the issue. Example options include:

- Immediate plant shutdown or placement in other safe condition
- Plant shutdown within a specified time period
- Continued operation with the implementation of compensatory actions (e.g., continuing operation at reduced power until the next refueling outage, or continuing operation with increased monitoring)
- Delaying the decision until more information is available

For each identified option, the team should identify the potential impact on the principles of risk-informed decision-making.

*Acceptance Guidelines or Criteria for Decision Options* – The team should define the basis for acceptability or rejection for each decision option. All five principles of risk-informed decision-making must be considered.

*Note: For the assessment of the acceptability of a change in risk, Regulatory Guide (RG) 1.174 (Ref. 2) provides appropriate acceptance guidelines. In some cases, the RG 1.174 acceptance guidelines may not be directly applicable. In such cases, it may be possible to qualitatively argue that any risk increases are small and consistent with the intent of the Commission's Safety Goal Policy Statement. For example, it may be possible to show that compensatory measures are effective in minimizing the risk impact.*

Table C-1 provides a convenient format for capturing the options that were considered to address the emergent issue, and the analysis approach, affected principles or factors, evaluation criteria, and other factors that may impact the decision.

Perform Assessment of Each Decision Option (Step 3)

In this step, technical staff assigned to work on this issue will analyze and document the assessment of each option. The analysis should be structured to parallel the five principles of risk-informed decision-making given in RG 1.174 and addresses the following:

- compliance with existing regulations
- maintenance of adequate safety margins
- maintenance of adequate defense-in-depth
- demonstration of acceptable levels of risk
- implementation of defined performance measurement strategies

Appendix D provides a detailed list of items to consider for each of the five principles of risk-informed decision-making.

For each analytical method used to support the technical analysis, an assessment of the technical adequacy of that method for the purpose of that analysis should be documented. Document the analysis of each input to the decision in a similar manner, addressing the following:

- What is affected by the issue
- How the option addresses the issue
- The uncertainties associated with the analysis
- The assumptions made to deal with those uncertainties
- The degree of confidence in the conclusion of the analysis

| Table C-1: Decision Options | | | | | |
|---|---|---|---|---|---|
| # | Option[1] | Analysis Approach[2] | Affected Principles or Factors[3] | Criteria used to Evaluate Options[4] | Other Items to Consider[5] |
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Notes:

1. Define each decision option (e.g., shut down plant immediately or shut down in specified time period)
2. What analytical tools are available (e.g., risk analysis tools or engineering models) – may be quantitative or qualitative
3. Identify potential impact on the principles of risk-informed decision-making. RC = compliance with regulations; DID = defense-in-depth; SM = safety margins; RM = risk metrics; PM = performance measurement strategies.
4. Define the basis or standard for accepting or rejecting each decision option.
5. Other items may include: Resource limitations, needed technical area expertise, NRC organizations needed to support the analyses, tools available, and time available to make decision.

For each analysis performed, the technical adequacy of the methods and information/data used must be documented. For example, in the case of the PRA model, its technical adequacy to support the application can be established using RG 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities” (Ref. 14). For decisions involving passive components, an assessment of the adequacy of the specific degradation model, structural integrity model, and inspection information should be provided (refer to Ref. 15).

The result of this step is a summary of the analysis for each decision option. Table C-2 provides a convenient format for capturing the assessment of each option that was considered, including driving factors and key technical inputs related to each option

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 decision-making. The team should also identify the preferred option from among the acceptable ones, including the justification for it being preferred. Table C-2 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 to recommend to the decision authority can sometimes be a contentious team activity. Appendix E 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 NRC’s non-concurrence process as set forth in Management Directive 10.158, "NRC Non-Concurrence Process" (Ref. 10). The LIC-504 process can proceed in parallel with the non-concurrence process. Cognizant NRC management should decide whether to continue the LIC-504 assessment on the originally planned schedule or to delay the assessment pending completion of the non-concurrence process. In any event, the decision authority should be fully informed of any non-concurrences relating to the issue under consideration in addition to the recommendation being made by the LIC-504 team.

The LIC-504 team should also consider what, if any, performance monitoring strategies should be put in place along with the recommended action. 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 C-2: Assessment of Decision Options | | | |
|---|---|---|---|
| Option #: Description:<br>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] |
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Notes:

1. The driving factors are the assessments of those principles of integrated decision-making 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 only be 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. Note that other "driving factors" may exist and may be included, as appropriate, in addition to the 5 key principles.
2. A key technical input is an essential input to the analysis that enables the conclusion of acceptability or non-acceptability to be reached. There may be several key technical inputs. For example, when assessing 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. This 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, recognizing the uncertainties in the technical inputs.

**2 – Communicate Assessment and Recommendations to the Decision Authority (Step 5 of Figure 2)**

The purpose of this step is to provide the decision-makers with the information they need to make a properly informed decision. A communication document should be prepared that can convey the essential information. Although slides containing brief lists of topics can be used to facilitate meetings, slides are typically not sufficient to accurately convey and document the material that the decision-makers will use to make the decision.

Decision-makers 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 that is to be made. Include the summary and characterization of the issue.

Decision: The decision that is required should be stated clearly and concisely.

Options: Each of the options developed in Steps 2 through 4 should be presented individually and concisely. The preferred option should be presented first. The driving factors for accepting or rejecting the option must be presented. Typically these factors address satisfaction or non-satisfaction of the principles of risk-informed decision-making 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. Other relevant criteria must also be addressed, if any. It is not sufficient to merely reference the Attachments to convey the logic of the conclusions and recommendation. The Attachments will be used as supporting documentation, but the communication document must provide sufficient information to document the logical basis for accepting and rejecting options.

Recommendation: The logic for accepting the recommended option and rejecting other options must be summarized, drawing from the individual option discussions. Where more than one option is acceptable, the basis for preferring the recommended option must be provided.

Supporting Details: Briefly describe any technical issues that are particularly important for the decision-maker in order to make a properly informed decision. Decision-makers need narrative descriptions that provide qualitative insight into causes, uncertainties, assumptions, sensitivities and affected outcomes for a given situation. Less information is needed regarding the details of numerical results, statistical methods, and analyses. This background information must be available, but it should be presented in the communication document only as necessary, and only in summary form, after recommendations. References to the detailed documentation should be provided in any summaries that are included.

Recommended Performance Monitoring Strategies: Provide details on any recommended performance monitoring strategies that should be put in place 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: A list of staff contacts for each relevant issue or input to the document should be provided at the end of the document.

When the above information is presented to decision-makers, 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 decision-makers 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.

**3 – Decision Authority makes the Decision**

The decision authority, using the information provided in the briefing and any other information he or she deems relevant to the issue, decides what should be done to address the emergent issue. The decision might be to implement the option recommended by the LIC-504, or it may be to implement some other action. The decision could even be to not take any action. The decision authority should also consider any recommended performance monitoring strategies and determine what performance monitoring, if any, should be put in place to monitor whatever action has been 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 that the decision maker be provided with the best information available, including limitations and uncertainties in the technical analyses that support any recommendation, to facilitate good decisions.

The decision authority should communicate his or her basis for the decision, so that basis can be documented (next step). This basis should be fairly detailed when the decision is to adopt some course of 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 GAO report (Ref. 5).

**4 – Document the Decision including Performance Monitoring (Step 6 of Figure 2)**

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

- Insights obtained from the decision-maker
- How various factors were considered in reaching the final decision
- 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 decision-maker to the director of NRR (or another appropriate addressee determined by the Management Lead). The documentation of decisions made using LIC-504 should be entered into the Agency-wide Documents Access and Management System (ADAMS).

If the issue and associated analyses warrant, a report may be generated to document the process that was followed, the analyses that were performed, the integrated assessment of options, the recommendation, and the final decision. Table C-3 provides an outline that may be used to help structure such a report.

**5 – Communicate the Decision (Step 7 of Figure 2)**

The decision and related information should be communicated as appropriate to the issue under consideration. If a communication plan was developed, it should be used to ensure that appropriate stakeholders are informed of the decision. In all cases the documentation of decisions made using LIC-504 should be entered into the Agency-wide Documents Access and Management System (ADAMS).

{LIC-504 Detailed Approach Ends}

Table C-3: 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 C-2, Assessment of Decision Options
- Communication to decision-maker (document, slides, briefing materials)
- Detailed analysis files, or references to those analyses

## Appendix D

## Risk-Informed Evaluation Worksheet

## Office Instruction LIC-504
## Integrated Risk-Informed Decision-Making Process for Emergent Issues

Note: This worksheet is a convenient way of documenting the risk-informed evaluation of any options developed to address the issue. It is not intended that every item listed for possible consideration be addressed; rather, the worksheet is intended to provide a large list of items to consider, only a portion of which may be applicable to a given issue or option. When documenting an analysis, the user should address only the items that apply to an option or issue and that will differentiate among various options.

A risk-informed evaluation is used to assess the emergent issue (Step 1) and each option (Step 3) identified during the LIC-504 process. This Worksheet is structured to parallel the five principles of risk-informed decision-making given in RG 1.174 and addresses the following:

- compliance with existing regulations
- maintenance of adequate safety margins
- maintenance of adequate defense-in-depth
- demonstration of acceptable levels of risk
- implementation of defined performance measurement strategies

This worksheet provides a template 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

Note: For each analysis performed, document the technical adequacy of the methods and information/data used. For example, in the case of the PRA model, its technical adequacy to support the application can be established using RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." For all analyses, both risk assessments and traditional engineering approaches, it is important to convey to the decision maker the analyst's degree of confidence in the analysis, as well as any assumptions and limitations.

### 2.1 Compliance with Regulations

Caution: Proposed options can create regulatory compliance challenges that were not present with the emergent condition. Further analysis may be necessary to determine compliance with regulations for some options. For example, a proposed option may involve an innovative compensatory measure that would require a dose assessment to ensure Part 100 limits were still met. Any regulations that may not be met should be identified and assessed in this section.

Note: Step 1 of the risk informed decision making process (Characterize the Emergent Issue) will identify the regulations that may be compromised by the emergent issue. If an option has no impact on the Step 1 evaluation, or has identical impact to another option that has been documented, the analyst may so state and reference the applicable analysis. There is no need to duplicate the information.

- Which, if any, regulations are potentially compromised by the issue?
- Does the issue affect the plant's design and licensing basis or generic letters which specify how the licensee satisfies certain basic regulatory requirements, such as diversity, redundancy, defense-in-depth, and the general design criteria?

  *Note: The plant's licensing basis could include technical specifications, license conditions, final safety analysis report, etc.*

  *Note: NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," (Ref. 16) provides useful information for this part of the assessment.*

- Identify analysis needed to demonstrate compliance with the regulations.
- Document the analysis performed to assess whether the regulations are met.

- Document the uncertainties.

  *Note any unrealistic or conservative assumptions used in the analysis.*

- Does the option impact compliance with regulations in a different manner than the impact of the emergent issue? Explain why this is an acceptable option from the perspective of compliance with regulations.

  *Note: The analyst should re-visit the base-case analysis to determine what, if anything, has changed for the option under consideration.*

## 2.2 Defense-in-Depth

Note: The assumption is as follows: given that the plant, at least before the condition/issue arose, met the regulations, there is adequate defense-in-depth. Therefore, the analysts should assess the effect of the condition/issue on defense-in-depth. The analyst should also assess the effectiveness of any compensatory measures.

- Which of the following high level aspects of defense-in-depth is affected by the issue?
  a) prevention of core damage
  b) prevention of containment failure
  c) barrier integrity (fuel cladding, reactor coolant system (RCS), containment)
  d) emergency preparedness

  *Note: The focus below will be on a), b), and c) since these are more directly amenable to risk-informed resolution.*

### *2.2.1 Assessment of impact of issue on prevention of core damage or containment failure*

This section documents the analysis of the impact on defense-in-depth with respect to items a) and b) above.

- Assess whether the issue results in the loss of redundancy or diversity, or a potential increase in unreliability or unavailability associated with a key safety function or a system associated with a key safety function, etc.

  *Note: Key Safety Functions include reactivity control, reactor pressure control, reactor inventory control, decay heat removal, and containment integrity*.

- Assess whether new common cause failure mechanisms or dependencies are introduced, or whether existing common-cause failure probabilities are increased. Consider:

  (i) Functional dependencies—Does the issue impact a system or function that supports multiple mitigating systems or functions?
  (ii) Phenomenological dependencies—Does the issue involve failures, such as strainer plugging, that can result in multiple equipment failures? Can the issue result in a harsh environment caused by radiation, temperature, pressure, etc., that can result in multiple equipment failures?
  (iii) Human interaction dependencies—Does the issue result in the need for operator action for which an error could contribute to multiple component failures?
  (iv) Component hardware failure dependency—Does the issue relate to factors that could cause failures of similar components, such as common problems with design, manufacturing, installation, calibration, or operational deficiencies?
  (v) Spatial dependencies—Does the issue result in an increased vulnerability to failure of multiple components resulting from being in a defined space or area, for example by events caused by internal flooding, internal fires, seismic events, turbine and other missiles, or other external event initiators?

- Assess whether defenses against human errors are preserved. (The questions are intended to characterize the way in which defense-in-depth is affected.)
  (i) Does the issue require the implementation of new operator actions or create new dependencies between operator actions?
  (ii) Does the issue involve plant procedures, operator training, or equipment/indicators that support operator actions such that one or more of these would be adversely affected, thereby affecting operator performance significantly?
  (iii) Does the issue significantly affect the amount of time for operators to take actions to recover from an accident?
  (iv) Does the issue adversely affect the environment in which the operators have to perform their actions?

### *2.2.2 Assessment of impact of issue on barrier integrity*

- Assess impact on barrier integrity (i.e., degradation of the effectiveness of barriers). *("Barriers" in this case is defined as the fuel cladding, reactor coolant pressure boundary, and containment structure.)*

  (i) Does the issue significantly change the failure probability of any individual barrier?
  (ii) Is the degradation mechanism understood and information (e.g., test or operational data) available regarding the degradation-time relationship for short-term and long-term solutions?
  (iii) Is the independence of barriers compromised? If so, which barriers?
  (iv) Does the issue introduce new or additional failure dependencies among barriers that significantly increase the likelihood of failure compared to the existing conditions?
  (v) Does the issue result in a significant increase in the existing challenges to the integrity of the barriers?

### *2.2.3 Assessment of potential for impact on multiple layers of defense-in-depth*

- Are the remaining elements of defense-in-depth intact? What are they and what is the reason for assuming they are intact?

  *Note: The intent of this question is to ascertain that the independence of the different layers of defense-in-depth is not compromised.*

### *2.2.4 Assessment of whether the risk model can address the defense-in-depth element*

- Can the impact of the degradation be quantified and evaluated through the risk model?

  *Note: Risk quantification may be reasonably straightforward, for example, for cases where there is a clear loss of redundancy, but it may be more difficult for cases where there are degraded states. If risk can be quantified, the results from Step 3 (perform assessment of each decision option) would provide additional insights into the effects of loss of defense-in-depth. If the impact cannot be readily quantified as input to a PRA model, a qualitative analysis may be necessary.*

### *2.2.5 Assessment of effectiveness of option in maintaining defense-in-depth*

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

- Does the option propose actions that can compensate for the degradation of defense-in-depth?
  *(Note: This may be proposed by the licensee or by the NRC. This may be part of a description of an option and would transfer to Step 2 (define decision options)).*
- Discuss the proposed actions. Explain how and to what degree the action(s) can be successful (what level of confidence can be associated with this compensatory measure).

- Does the option identify a programmatic activity that is proposed as a compensatory measure for the identified issue?
  *Note: For example, reliance on operators as monitors of plant conditions.*

- Describe how the option addresses degradation of defense-in-depth.
- 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.
- List assumptions made to address the uncertainties and how they support the option. Assess the confidence level in the option.
- Document why the methods used in the analyses above are considered adequate to support the conclusions.

## 2.3 Safety Margins

### *2.3.1 Assessment of issue on safety margin*

- Define "safety margins" relevant to this application.
  *Note: Margins can be (1) conformance to codes and standards or their alternatives approved for use by the NRC, (2) design margins, (3) safety margins or safety limits, or (4) safety analysis acceptance criteria in the licensing basis.*

- What is the basis for the original safety margin and how much conservatism was built in?
  *Note: This may be difficult to obtain—original regulatory or licensing basis documents may not be readily available.*

- Where was safety margin lost or degraded?

- Identify which aspect of safety margin is compromised and describe the impact. Provide an assessment of the actual extent of loss of safety margin, if measurable or otherwise determinable.

- Document an assessment of the significance of the loss of safety margin, including assumptions made as to the degree of loss, and the expected consequences of functional failure of the affected elements. Document the uncertainty associated with an evaluation of the available margin. *Note: The results of this assessment can be used to guide the uncertainty evaluation for the risk analysis and will provide useful information to help in the overall decision-making process. In evaluating safety margins, we can also look at the risk profile of the plant. It would be important for the decision-maker to know if the issue creates or exacerbates a situation where risk is dominated by a few elements (SSCs or operator actions) or a few accident sequences.*

- Can the loss of safety margin be quantified in such a way as to provide input to a PRA evaluation?
  *Note: This would require existence of a model that translates the safety margin loss into increases in failure probability, for example. This is likely beyond current model capability for most issues that may arise.*

### *2.3.2 Assessment of option on safety margin*

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

- Describe how the option addresses such degradation in safety margin.
  - Are there measures that can be taken to compensate for the potential impact of loss of margin?
  - Describe any compensatory measures and how they address this degradation.

  *Note: Compensatory measures may be proposed by the licensee or by the staff. Compensatory measures may help to identify potential options to address the issue. For example, compensatory actions could take the form of monitoring the rate of degradation. Proof of viability would likely require an assessment of the significance of the initial degradation.*

- Identify sources of uncertainty with respect to (1) the assessment of the impact of the degradation of safety margin (the base case), and (2) either the compensatory measures or monitoring approach (the option).
- List assumptions made to address the uncertainties and how they support the option. Assess the confidence level in the option.

- In decisions involving passive components, provide an assessment of the adequacy of the specific degradation model, structural model and inspection information.

- Document why it is considered that the methods and data used in the analyses above are adequate to support the conclusions.

## 2.4 Risk Assessment

Note: The purpose of the risk assessment is to provide any available risk insights to the decision-maker. Not all issues or options are amenable to analysis using a PRA model or other risk assessment. The risk assessment may use any number of techniques or methods, including, but not limited to, bounding analyses, fault-tree/event tree models, likelihood/consequence estimates, initiating event impact assessment, event sequence analysis, etc. Emergent issues frequently involve plant conditions that are not readily analyzed using the PRA model; the analysts should endeavor 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. The information provided to the decision-maker may be qualitative in many cases; engineering judgment should be employed to properly characterize the risk insights developed.

Note: The acceptance guidelines in RG 1.174 (Ref. 2) and RG 1.177 (Ref. 17) may not be applicable in cases where core damage frequency (CDF) and large early release frequency (LERF) cannot be readily estimated. An example would be the degradation of a pressure boundary due to an active process. It would not make sense to try to calculate an increased loss-of-coolant accident (LOCA) frequency for this case, though 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:

- CDF and change in CDF (RG 1.174)
- LERF and change in LERF (RG 1.174)
- Incremental conditional core damage probability and incremental conditional large early release probability (RG 1.177)
- Large release frequency or change in large release frequency
- Core damage probability or large early release probability
- Conditional core damage probability or conditional large early release probability
- 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
- Qualitative Health Objectives

### *2.4.1 Determination of How to Assess Risk*

- 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 provide a justification for its basis.

*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) an actual unavailability of an SSC, (4) a possibility of failure under certain conditions.*
- Given this characterization, what risk assessment results can be generated to provide insights for the decision-maker? *Note: For examples (1) and (3), it may be possible to calculate CDF or LERF metrics, but for (2) and (4) probably not. 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 conditional core damage probability. 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.*
- Describe the analysis process.

- 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)? Include a discussion of the uncertainty associated with such judgment.
  *Note: The goal here is to identify to the decision-maker the potential impacts the issue or option has on risk. The absence of quantitative information should not preclude providing and documenting any risk insights that can be developed by the analysts.*

### *2.4.2 General Scope of Risk Assessment/PRA*

The analyst needs to consider whether all sources of risk that may be significant and relevant to the issue or the option being evaluated have been considered. The scope of the risk assessment will vary depending upon the issue or option. Document the scope of the risk assessment, including any PRA models, considering the guidance below.

- Does the issue impact the availability and performance of SSCs, or potential effect 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 is "Yes" to any of the questions, 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 is "Yes" to any of the questions, 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 loss-of-coolant accidents)? Does the issue involve mechanisms that could cause failure of containment isolation? Does the issue impact containment systems (including $H_2$ igniters) or systems needed to mitigate the release of radioactive material in the short term? Does the issue affect RCS depressurization?
  *Note: If the answer is "Yes" to any of the questions, then the risk analysis should also consider large early release frequency 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 is "Yes" to any of the questions, 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:
  - 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 effects of changes made, compensatory measures, or performance monitoring? If so, describe how this effect was included in the analysis.
  - Consider uncertainty in the risk assessment using the guidance in RG 1.174. Additional information on treatment of uncertainties in PRAs may be found in NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making" (Ref. 18). 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
  - Assess the impact of those uncertainties on the conclusions of the risk assessment.
  - 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 set forth in Regulatory Guide 1.174 (Ref. 2) is that the impact of a proposed change should be monitored using performance measurement strategies. For a decision on what action NRC should take in response to an emergent issue, the staff should consider whether performance monitoring strategies should be implemented to verify that the desired results are obtained and any adverse, unintended consequences are discovered.

| |
|---|
| Assess proposed performance measurement performance monitoring measures. *(These could be introduced, either by the staff or the licensee, and may help define potential options for addressing the issue.)* |

| |
|---|
| For any performance monitoring strategy, describe the intent (including how it will provide confidence that the results and assumptions of the underlying engineering analyses or other evaluations remain valid). Describe the assumptions related to implementation of these strategies or measures. *Note: Monitoring may be initiated for a number of reasons, but typically it is used to provide a feedback loop and to validate the assumptions made to support the decision. Different decision options may rely on different aspects of performance monitoring.* |

| |
|---|
| Describe how monitoring will achieve its purpose in a timely manner. *Note: For monitoring to be effective, there has to be clear performance criteria, the metric used should be amenable to measurement, and the metric must be sensitive enough to provide sufficient margin.* |

| |
|---|
| Describe potential risk management strategies, including compensatory measures (if any), and discuss how the efficacy of these measures can be evaluated. Consider what performance measurement strategies are needed to confirm assumptions, analysis limitations, or other measures put in place to offset incompleteness or uncertainties in the engineering or risk analyses (data and models). |

## 3. CONCLUSIONS

## 4. REFERENCES

## Appendix E

## Reaching Consensus on a Recommendation

## Office Instruction LIC-504
## Integrated Risk-Informed Decision-Making Process for Emergent Issues

This Appendix is intended to assist the risk management team in reaching a consensus during Step 6 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., PRA, engineering, licensing) will participate in the integration process. The goal of this step is to come to agreement on a recommendation to take forward to decision-makers. 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.
- With the help of the team leader, decide upon a decision option to recommend to decision-makers. As part of these deliberations, the following questions should be considered for each input to 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/conclusion?
        - What is the significance of the results?
    - In the case that an individual assessment does not support 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 whom decision option is considered “preferred” for taking forward to decision-makers.

Given the potentially subjective nature of the risk-informed process, the team may not be able to reach a consensus. 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 decision-maker along with the recommended decision option(s).
- Iterate back through the process and conduct additional analysis.
- If the disagreement cannot be reconciled by additional information or analysis, seek management guidance to review the analysis and make a decision based on available analyses.

In some instances, individuals may enter NRC’s non-concurrence process as set forth in Management Directive 10.158, "NRC Non-Concurrence Process" (Ref. 10). The LIC-504 process can proceed in parallel with the non-concurrence process. Cognizant NRC management should decide whether to continue the LIC-504 assessment on the originally planned schedule or to delay the assessment pending completion of the non-concurrence process. In any event, the decision authority should be fully informed of any non-concurrences relating to the issue under consideration in addition to the recommendation being made by the LIC-504 team.