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

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.:	LIC-504, Revision 3
Office Instruction Title:	Integrated Risk-Informed Decision-Making Process for Emergent Issues
Effective Date:	April 12, 2010
Approved By:	John A. Grobe
Date Approved:	April 7, 2010
Primary Contacts:	Steven A. Laur (301) 415-2889 steven.laur@nrc.gov Donald G. Harrison (301) 415-2470 donnie.harrison@nrc.gov
Responsible Organization:	NRR/DRA

Summary of Changes: This is Revision 3 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 feedback and comments received after using this procedure to support decision-making in actual emergent issues (documented in ADAMS ML070990071 and ML081580560). The conditions for entering into this office instruction have been clarified. Both "standard" and "detailed" approaches are provided.

Training:	Self study
ADAMS Accession No.:	ML100541776

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Training: Self study

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Position	DRA/NRR	DRA/NRR	DCI/NRR	DORL/NRR	DORL/NRR	
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Date	02/24/2010	02/24/2010*	02/24/2010*	03/12/2010	03/12/2010	
Position	DRA/NRR	DCI/NRR	DE/NRR	DSS/NRR	DPR/NRR	DORL/NRR
Name	MCunningham	MEvans	PHiland	WRuland	TMcGinty	JGiitter
Date	03/2/2010*	03/18/2010*	03/18/2010*	03/12/2010*	03/18/2010*	03/17/2010
Position	DLR/NRR	DIRS/NRR	PMDA/NRR	NRR/DD	NRR/DD	
Name	BHolian (SSL for)	FBrown (MC for)	MGivvines (KFerrell /f/)	BBoger	JGrobe	
Date	03/19/2010	03/24/2010*	04/5/2010	04/6/2010	04/6/2010	

* concurrence via e-mail

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NRR OFFICE INSTRUCTION
LIC-504, Revision 3

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 to meet the agency's performance goals. In particular, we will undertake the following:

- Develop, maintain, and implement licensing and regulatory programs to protect public health, safety, and the environment
- Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulation
- Use domestic and international operational experience and events to enhance decision-making
- Conduct safety oversight programs, including inspections and enforcement activities, to monitor licensee performance
- Use risk-informed and performance-based approaches, where appropriate, to ensure that regulatory programs are conducted consistent with an appropriate level of risk
- Consider stakeholder-suggested improvements to the regulatory framework and take action to address regulatory practices that impose unnecessary burden
- Establish specific goals for continuous improvement in programs and processes

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 reactor-based, risk-informed decision-making, although it is considered that the basic steps can be followed for other risk-informed applications. 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," Revision 1, issued November 2002 (Ref. 1); MD 8.3, "NRC Incident Investigation Program," issued March 27, 2001 (Ref. 6); and LIC-401, "NRR Reactor Operating Experience Program," issued May 17, 2005 (Ref. 7)). Therefore, the guidance in this document, in particular the templates in Appendices B and C, can be supplemental to existing risk-informed processes, but was specifically developed for risk-informed decisions that are not already covered by established processes.

All risk-informed processes share the same major elements that serve as the foundation of sound risk-informed decision-making. These elements include compliance with existing regulations, maintenance of safety margins, adequate defense-in-depth, acceptable levels of risk, and defined performance measurement. The processes generally differ in the manner by which they demonstrate that the elements are satisfied.

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. 2), the U.S. Government Accountability Office (GAO) 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, LIC-504 guidance focuses on documenting those inputs so that their contribution to the resulting decision can be clearly understood. 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, LIC-106 or the NRC Enforcement Manual process should be entered. If LIC-504 is implemented, it 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.

The risk-informed decision-making process may be applied to a variety of emergent issues, some relatively straightforward and others very complex. Therefore, both standard and detailed approaches for using this instruction are provided. The standard approach provides the same basic framework for thinking about an issue and documenting the resulting decision as the detailed approach, but is much simpler and less resource-intensive than the detailed approach. The detailed approach 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.

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.

4.1 Entering LIC-504

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 choice of the standard or detailed approach provided herein should be based on attributes of the emergent issue, as discussed in more detail below. 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.

Figure 1 provides a flow chart as an aid in determining whether LIC-504 should be entered and whether the standard or detailed approach is appropriate. The flow chart provides general guidance, but should not be taken as prescriptive.

The flow chart has three general screening questions that may result in the user opting out of LIC-504. The fourth decision box contains a series of questions to aid the user in determining whether to use the standard or detailed approach.

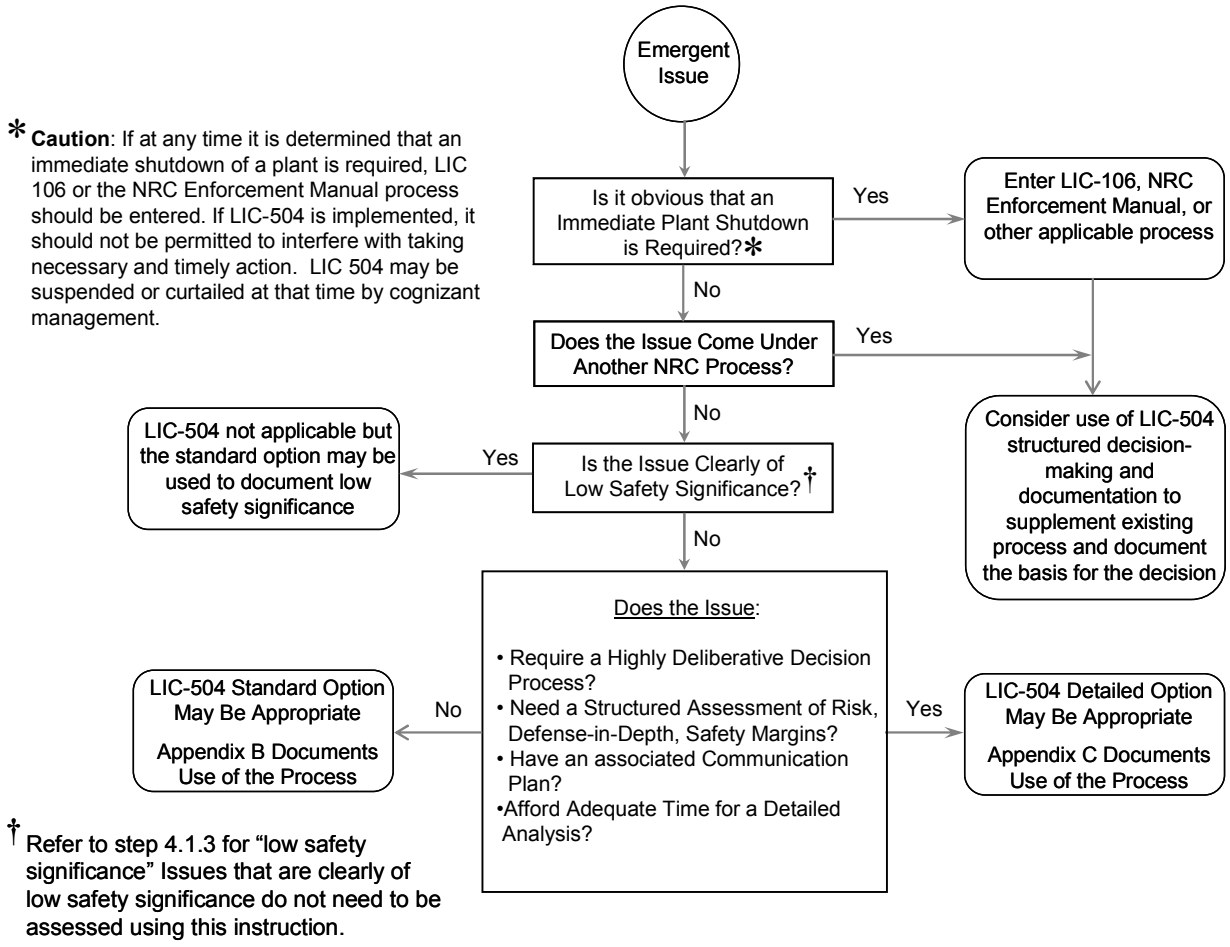

FIGURE 1: ENTERING LIC-504

4.1.1 Is an Immediate Shutdown Required?

The first GAO recommendation (Section 3 above) involved guidance for when to shut down a nuclear power plant. NRC has such guidance in place. If, at any stage of the evaluation, it is determined that regulatory action is needed to place or maintain a plant in a safe condition, LIC-106 or the NRC Enforcement Manual process should be entered. 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 both internal and 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.

4.1.2 Does the Issue Come Under Another NRC Process?

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.

However, division management may direct that LIC-504 be used to supplement the existing procedure or process; e.g., to provide a documented, rational evaluation of options in a risk-informed manner. In such cases, the standard approach (Appendix B), or portions thereof, would likely be sufficient to assess the issue.

[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.

4.1.3 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.

4.1.4 Choosing the Standard or 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. The selection of the approach to use should consider a number of factors. Because the level of resources necessary to complete the detailed process may be considerable, the standard process is considered the default.

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

<u>Need for Highly Deliberative Decision Process</u>

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.

<u>Need for Structured Assessment of Risk, Defense-in-Depth, Safety Margins</u>

The detailed approach is useful when a structured assessment of the five key principles of risk-informed decision-making (compliance, defense-in-depth, safety margins, risk, and performance measurement) 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 the standard approach, the differentiating factor or factors need not be from among the five key principles.

Need for Associated Communications Plan

In cases where a formal communication plan is needed, the detailed approach of LIC-504 may be appropriate. 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 process 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

Appendix B should be used for those issues where the standard approach in this Office Instruction 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 analyst may use or modify the forms as desired.

4.2 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. These steps are discussed separately below. The process is expected to be an iterative one, and Figure 2 illustrates this through the feedback loops shown with dashed lines. 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.

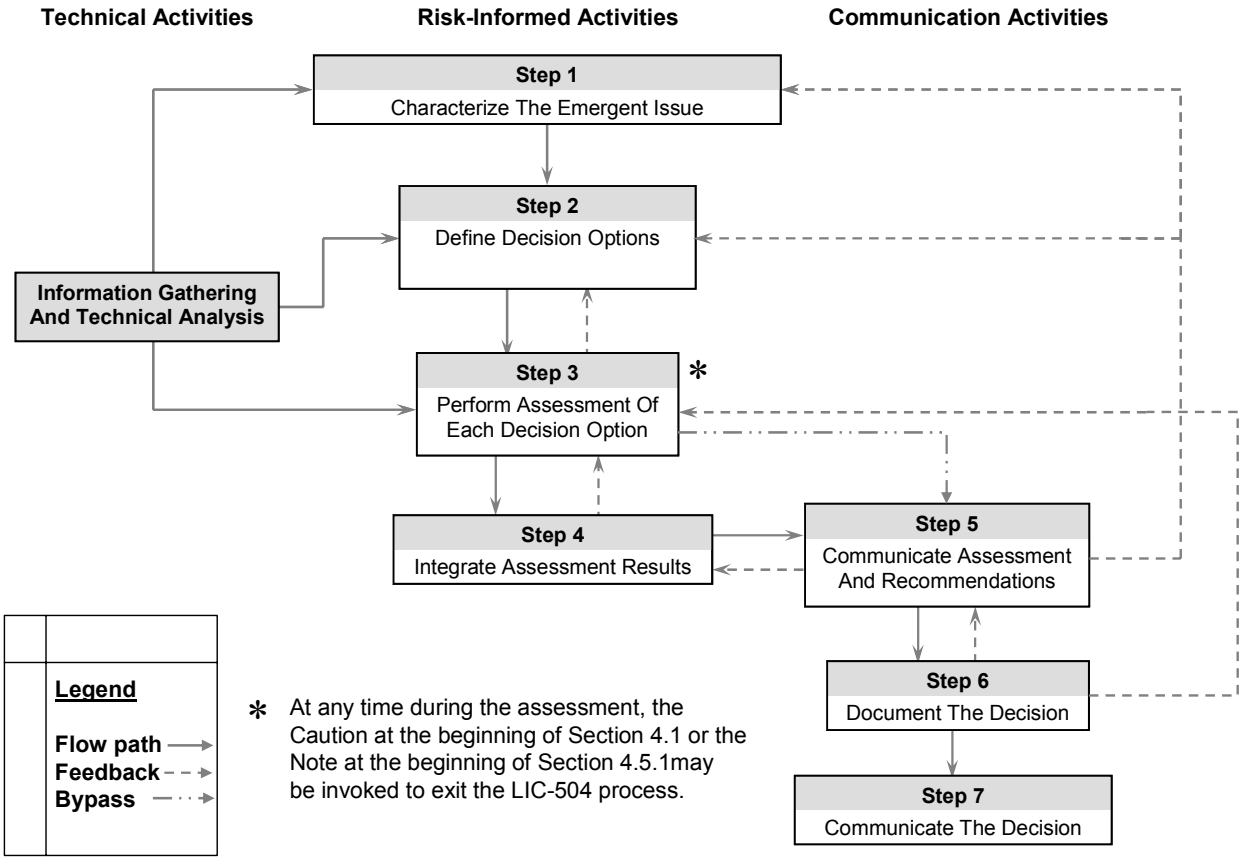

FIGURE 2: RISK-INFORMED DECISION MAKING PROCESS

This instruction provides two templates for documenting the results of these activities in a manner that supports their use in decision-making: Appendix B provides a template for the standard approach; Appendix C provides the detailed approach template. 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.

Figure 2 depicts three different areas—technical activities (information gathering and analysis, which provides input to Steps 1-3), the risk-informed decision-making process itself (Steps 1 - 4), and communication of the decision (Steps 5 - 7). The guidance on Steps 5 - 7 is specific to this process but was developed from more generic, existing NRC guidance.

Steps 1 - 3 in this process are common to other risk-informed decision-making processes (e.g., Ref. 1). Information is gathered and technical analyses performed at this point in the process. These steps 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 (Ref. 1). However, RG 1.174 and related documents only briefly discuss this important step. Therefore, this office instruction provides additional guidance for documenting assessment results.

Steps 5 - 7 have been separated to highlight the importance of communicating the decision and to emphasize the need to use recently developed guidance for risk communication (Refs. 3 and 4). The feedback loop from Step 6 to Step 3 reflects the potential need for additional analyses to clarify initial results or answer questions that were not previously considered.

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. Any suitable format may be used, provided the resulting report appropriately documents the emergent issue, options considered, bases for the recommended option, and the decision that was ultimately reached.

The process should be followed until there is sufficient confidence in the recommendation to allow the decision-maker to select an option to address the issue. The effort to achieve “sufficient confidence” may vary greatly, depending upon the issue. Figure 2 shows a path from assessment of decision options (Step 3) to communicating the assessment and recommendations (Step 5), bypassing the integration of results (Step 4) when compelling reasons make a formal integration of the analysis unnecessary (e.g., when an immediate plant shutdown is required (see Section 4.2), or when it is clear that the risk implications are minor (see note at start of Section 4.4.1). Whether the process is fully implemented or truncated, documentation of the effort is important. For example, a decision to maintain “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 the detailed implementation of this instruction is warranted, a Communication Plan 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. 3 and 4) 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 4.1 and Figure 1.

The cognizant manager for a given emergent issue should determine whether LIC-504 should be implemented for that issue. When LIC-504 is implemented, the cognizant manager should identify the decision authority, identify the NRC organizations that will be involved in making the decision, and assign a technical lead.

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

All NRR Staff Members

All NRR staff members are responsible for assisting their managers in keeping the primary contact informed of integrated risk-informed decision-making activities. The staff should also report to the primary contact any problems with, or possible improvements to, this office instruction.

When assigned to be a technical lead for an issue where LIC-504 is implemented, the individual will recommendation to the cognizant manager whether to use the standard approach or the detailed approach. The technical lead will coordinate the activities of all individuals assigned to the decision-making process for that issue.

Primary Contact

The primary contact 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

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 overseeing the activities of the primary contact and helping the primary contact develop, implement, and maintain the office instruction. The responsible manager may, as necessary, reassign or coordinate the reassignment of an office instruction to a new primary contact. The responsible manager may approve minor revisions to the office instruction. The responsible manager will ensure that the 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.

7. PRIMARY CONTACTS

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Donald G. Harrison, NRR/DRA
301-415-2470
donnie.harrison@nrc.gov

8. RESPONSIBLE ORGANIZATION

NRR/DRA

9. EFFECTIVE DATE

April 12, 2010

10. REFERENCES

1. U.S. Nuclear Regulatory Commission, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Regulatory Guide 1.174, Revision 1, November 2002.
2. U.S. General Accounting Office, “Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant’s Shutdown,” GAO-04-415, May 2004.
3. U.S. Nuclear Regulatory Commission, “Effective Risk Communication—Guideline for Internal Risk Communication,” NUREG/BR-0318, December 2004.
4. U.S. Nuclear Regulatory Commission, “Effective Risk Communication—The Nuclear Regulatory Commission’s Guideline for External Risk Communication,” NUREG/BR-0308, January 2004.
5. 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).
6. U.S. Nuclear Regulatory Commission, “NRC Incident Investigation Program,” MD 8.3, March 27, 2001.
7. U.S. Nuclear Regulatory Commission, “NRR Reactor Operating Experience Program,” LIC-401, May 17, 2005.
8. U.S. Nuclear Regulatory Commission, “Issuance of Safety Orders,” LIC-106, December 17, 2003.

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

   Attachment C-1, Risk-Informed Evaluation Worksheet

   Attachment C-2, 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 1			
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

Appendix B

Standard Approach to Risk-Informed Decision-Making

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

The decision to employ the standard approach of this instruction may be made by any member of the staff, by supervision, or by management. Completion of this approach may be by an individual or a team, depending upon the nature of the issue. There is no need to assign a technical integrator or team facilitator for implementing the standard approach of LIC-504. A communication plan would typically not be required for this approach.

Once it has been determined that the standard approach of LIC-504 should be 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 Section Chiefs, 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 making 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.

Assign a technical lead – Also, if necessary for the issue, form a technical team comprising sufficient resources to characterize the issue, define options, perform the analyses, and make a recommendation.

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

Table B-1: LIC-504 Process Initiation (Standard Approach)			
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			
Technical Lead			
Team Members			
ADAMS Accession No. _____			

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.

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

Table B-2: Decision Options					
#	Option[1]	Analysis Approach[2]	Affected Principles or Factors[3]	Criteria used to Evaluate Options[4]	Evaluation[5]

Notes:
1. Define each decision option (e.g., shut down plant immediately 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.

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-making given in RG 1.174 (Ref. 1) and addresses the following:

- Conformance with the regulations
- Maintenance of the defense-in-depth philosophy
- Maintenance of safety margin
- Control of changes in risk to ensure they are small
- Use of performance monitoring or compensatory measures

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 combined.

Integrate Assessment Results (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.

4 – Communicate Assessment and Recommendations (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 formal communication document may not be required. 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 of the issue, the options considered, the recommended option, and the basis for that recommendation.

5 – Document the Decision (Step 6 of Figure 2)

Once the decision has been made, the staff should document the decision. A memorandum or other communication may be used to document the final decision.

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

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.) 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 ATTACHMENTS As needed

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

The decision and related information should be communicated as appropriate to the issue under consideration. The documentation of the LIC-504 decision process should be entered into ADAMS.

{LIC-504 Standard Approach Ends}

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 employ 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). The Director of DRA will assign an individual to be the technical integrator and team facilitator for implementing LIC-504.

Once it has been determined that the detailed approach of LIC-504 should be applied to an emergent issue, the following steps are recommended.

1 – Initiate the LIC-504 Process

Because the detailed approach of LIC-504 involves a team, a communication plan, and a significant issue, a formal meeting is warranted to initiate the process. The following steps are recommended.

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 Section Chiefs, 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 making 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:

- Name a technical lead
- Request a technical integrator and team facilitator from DRA
- 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.
- Consider naming a communications lead
- 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.

Hold the initial team meeting to begin the process – Self-explanatory.

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

Table C-1: LIC-504 Process Initiation (Detailed Approach)			
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			
Technical Lead			
DRA Technical Integrator/ Team Facilitator			
Team Members			
Communication Team:	Name/Title	Organization	Telephone
Communication Lead			
Team Members			
ADAMS Accession No. _____			

2 – Develop the Communications Plan

A communication will generally be required for issues that warrant the LIC-504 detailed approach. A communication lead should be assigned to draft the Communication Plan. The Communication Plan will be updated throughout the process and be used to determine what to communicate during and after the process.

At the beginning of the process, the Communication Plan elements may not be known, and topics like "key messages" may change as the process proceeds. Therefore, the initial draft Communication Plan will evolve with the process. For example, an initial key message might be: "This is a complex issue and one that the NRC takes very seriously. Our staff is working hard to better understand the issues involved, and we will keep you informed as we conduct our analyses." After the completion of each subsequent step, and when a decision is made, the Communication Plan will reflect new key messages based on the new information. For additional information, refer to the internal NRC Communication Plan Guidance at:

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

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

The team 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). It is recognized that the decision-making process may be highly iterative, such that information gathered in this step may require supplementation as the process proceeds.

The team should identify the structures, systems, and components (SSCs) or operational characteristics affected by the issue (including human actions), and describe the nature of the effect on the identified SSCs or operational characteristics. Examples include: residual heat removal pump unavailable; degraded auxiliary feedwater pump performance; degradation of pressure boundary; hindered access for operator local action outside the main Control Room due to fire. Document the potential impacts on safe operation of the plant. For each SSC identified, the team should identify the safety function(s) affected and the plant conditions/ operating environments under which the issue would affect the safety of the plant.

The team should identify the regulations (or other requirements/commitments such as design basis, licensing basis, generic letters) that may be challenged by this issue. The team should assess the expected duration of the issue (when applicable).; e.g., how long the issue or condition has been present and whether the issue is/was a temporary condition.

The team should consider any source of information that may be expected to provide accurate and useful information bearing on the issue. Example information sources include the plant Updated Final Safety Analysis Report and Safety Evaluation Report, inspection reports, results of team inspections related to the issue pursuant to Management Directive 8.3, and incident reports.

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.

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 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-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, evaluation criteria, and other factors that may impact the decision.

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

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.

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 (Ref. 1) and addresses the following:

- Conformance with the regulations
- Maintenance of the defense-in-depth philosophy
- Maintenance of safety margin
- Control of changes in risk to ensure they are small
- Use of performance monitoring or compensatory measures

Attachment C-1 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

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.” For decisions involving passive components, an assessment of the adequacy of the specific degradation model, structural integrity model, and inspection information should be provided (Ref. 5).

The result of this step is a summary of the analysis for each decision option. Table C-3 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

Table C-3: Assessment of Decision Options			
Option #: Description: Preferred [ ] Acceptable [ ] Not acceptable [ ]			
Driving Factor[1]	Key Technical Inputs[2]	Characterization of the representation of the key technical input[3]	Characterization of confidence in the assessment of the driving factor[4]

Notes:

1. The driving factors are the assessments of those principles of integrated 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.

Integrate Assessment Results (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-3 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. Attachment C-2 provides guidance on reaching a consensus that may be useful to teams weighing the relative merits of various options.

4 – Communicate Assessment and Recommendations (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.

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.

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.

5 – Document the Decision (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 measurement 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).

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-4 provides an outline that may be used to help structure such a report.

Table C-4: Sample Report Format to Document LIC-504 Decision Process

EXECUTIVE SUMMARY

DESCRIPTION OF ISSUE

Background
Detailed Description of Issue

OPTIONS CONSIDERED

EVALUATION AND ASSESSMENT OF OPTIONS

Risk-Informed Evaluations
Integrated Assessment of Options

RECOMMENDATION

FINAL DECISION

ATTACHMENTS

Sample list:

- Table C-1, LIC-504 Process Initiation
- Communications Plan
- Table C-2, Decision Options
- Table C-3, Assessment of Decision Options
- Communication to decision-maker (document, slides, briefing materials)
- Detailed analysis files, or references to those analyses

The documentation of the LIC-504 decision process should be entered into ADAMS.

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

The decision and related information should be communicated to the various stakeholders in accordance with the Communication Plan developed in Step 1. Since the Communication Plan is a "living" document, it should be reexamined at this point to ensure that it addresses the right audiences and that the key messages reflect the process and its outcomes. Audiences may include internal and external stakeholders. Key messages may include the information conveyed in the decision communication, as well as background information relevant to specific audiences.

{LIC-504 Detailed Approach Ends}

Appendix C

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 (Ref. 1) and addresses the following:

- Conformance with the regulations
- Maintenance of the defense-in-depth philosophy
- Maintenance of safety margin
- Control of changes in risk to ensure they are small
- Use of performance monitoring or compensatory measures

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:

Attachment 1

ANALYSIS TEMPLATE AND GUIDANCE

1. BACKGROUND

- Document the boundary conditions.
- Include 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."

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: For the "initial risk-informed evaluation" (Step 1), the regulations that may be compromised are those related to 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.

- 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 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 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.

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. 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 and RG 1.177 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." 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

Document the performance measurement strategies and/or compensatory measures.

Assess proposed performance measurement and/or compensatory 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 measurement, 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 these measures can either offset the increase in risk and/or improve safety. Also describe how these measures can offset incompleteness or uncertainties in the engineering or risk analyses (data and models). Describe the assumptions related to how the strategies or measures impact the risk assessment.

3. CONCLUSIONS

4. REFERENCES

Appendix C

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.