

NRR Office Instruction
LIC-504 Revision 3
Self-Study Training Material*

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

** Suggest reading the “speaker’s notes” for each slide*

Title slide. If you are reading this, then you’re looking at the “speaker’s notes” and will get more out of the presentation!

Training Topics

- What's New in Revision 3?
- Why the Change?
- Entering LIC-504
 - Screening Questions
 - Selecting the Standard or Detailed Approach
- Review: The LIC-504 Process
- Summary
- Supplementary Information
 - Why LIC-504?
 - The 5 Key Principles of Risk-Informed Regulation

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The first three bullets explain what has changed in Revision 3 of LIC-504. The LIC-504 process has not changed, but is summarized here because the process itself is generic and can be applied to any decision process. The supplementary information is for interested readers and provides (1) the background as to why LIC-504 was written in the first place and (2) an introduction into the 5 key principles of risk-informed regulation.

Purpose

- The primary purpose of this training is to inform you of the changes in Revision 3 of LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues”
- The LIC-504 process is reviewed in brief
- Supplemental information is provided for interested readers

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You’ve completed the training once you get to the summary slide. The supplemental information is optional and is provided for the interested reader.

What's New in Revision 3?

- Provides two approaches (Rev. 2 only had one approach)
- “Standard Approach”
 - Used for issues that are relatively straightforward or may depend on only a few determining factors (more later)
 - Simpler than the detailed approach
- “Detailed Approach”
 - Not changed substantively from Rev. 2
 - Retains the original attachments for the assessment of the 5 key principles of risk-informed decision-making (with minor editorial corrections)
- Each approach presented in linear fashion for ease of use
 - Standard approach: Appendix B of LIC-504, Rev. 3
 - Detailed approach: Appendix C

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The detailed approach was the only method presented in earlier revisions of LIC-504. The standard approach allows the user to tailor the process, including what factors to consider, to the issue at hand. It should be noted that revision 2 had caveats to allow the user to pretty much modify everything in the process; however, users were not comfortable taking such liberties with the instruction – hence the “standard approach.”

The “linear fashion” refers to having to pick an appendix (“B” for standard approach; “C” for detailed) and staying in that guidance from start to finish – straight through. Revision 2 tried to build in the iterative nature of the process by branching out to other forms from the main process (similar to IRS tax forms), which turned out to be difficult to understand or follow.

Why the Change?

- Current revision is too complicated
 - Intended for major issues
 - Team approach, formal communication plan, technical integrator, and process facilitator indicated
- Many other issues could benefit from the LIC-504 decision-making process
 - For example, in both cases where it has been used to date,* the factors driving the decision were relatively few and well-understood

* *see LIC-504 analyses documented in ADAMS
ML070990071 and ML081580560*

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Both times LIC-504 was used, material issues (dissimilar metal butt-welds) were involved. The first ML number refers to the LIC-504 evaluation of Wolf Creek pipe cracks found in the pressurizer surge line and relief line nozzles. The second ML number refers to similar cracks found in a spared pressurizer that had been part of St. Lucie plant.

Rev. 3 Addresses User Feedback

- Provides better entry guidance
- Includes two approaches
 - Streamlined "Standard Approach"
 - Original "Detailed Approach"
- Clarifies process flow for either approach

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Revision 3 was created with input and critique from the primary user of LIC-504 in the past.

When to Enter LIC-504

- LIC-504 process should be entered for making and documenting risk-informed decisions when:
 - No other process applies
 - Management desires to supplement an existing process by providing a decision-making structure and formal documentation
 - Potentially risk-significant emergent issues are involved
 - Significant concerns about safety margin or defense in depth exist
 - Other risk-informed processes call for increased management attention
- The outputs of LIC-504 are:
 - The Decision
 - Communication of the Decision
 - Documentation of decision and basis (in ADAMS)

Note: Resources to invoke LIC-504 could be significant!

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Remember, the title of LIC-504 is “Integrated Risk-Informed Decision-Making Process for Emergent Issues.” It is not intended for all decisions, nor for non-risk-informed decisions. More importantly, the intent was to fill any gaps in our processes – not to supersede them. Therefore, if there is a process that applies to address a given issue, use that process! Only enter LIC-504 if management decides to supplement the other process in some way. On the other hand, if LIC-504 is appropriate for a given emergent issue, then tailor its use to the issue under consideration. LIC-504 provides guidance, not prescriptive direction.

When to Enter LIC-504

- Decision to enter LIC-504 **typically** made by Division Director with lead responsibility for the issue
- LIC-504 may be used
 - By itself when no other procedure applies
 - In conjunction with other procedures if directed by management
- Factors influencing the decision to implement LIC-504
 - Potential safety significance of the issue
 - Extent of condition and generic implications
 - Complexity of the issue
 - Level of interest of various stakeholders
 - Need for scrutable and defensible documentation of the decision
 - Uncertainty regarding the consequences of the decision

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Anyone may recommend that LIC-504 be entered, but, because it may be resource intensive, involve a number of organizations, or end up being highly visible, it is recommended that the lead NRR division director make the decision as to whether or not to implement LIC-504.

Note that the underlying criticism of the GAO (which LIC-504 seeks to address) is that the Davis-Besse decision was not documented in a scrutable manner, such that an after-the-fact audit could determine how and why NRC made the decision it did. Therefore, a key factor in deciding to implement LIC-504 might be to provide the scrutable and defensible documentation of the decision, even if the actual process followed resides in another instruction or procedure.

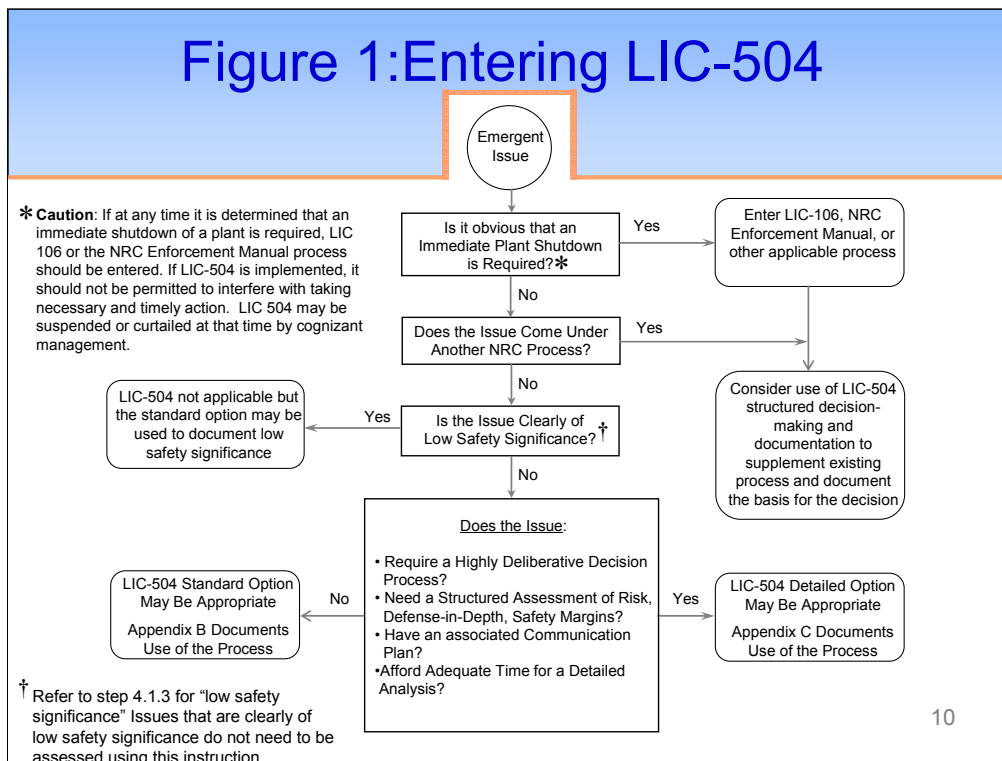
Entering LIC-504

- Figure 1 (next slide) provides a flow chart as an aid in determining whether LIC-504 should be entered
- Flow chart provides general guidance, but should not be taken as prescriptive
- Three screening questions (may opt out of LIC-504)
 - Obvious need to immediately shutdown a plant
 - Issue comes under another NRC process
 - Issue is clearly low safety significance
- Decision box to aid user in determining whether to use the standard or detailed approach

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This slide introduces Figure 1 from LIC-504. The next slide shows the figure itself. Subsequent slides discuss the decision boxes in Figure 1. Do not be shy about returning to the figure as you proceed through this part of the self-study.

Figure 1: Entering LIC-504



Take a few minutes to scan this figure. Note the frequent use of the word “may” in the various boxes. There is only one hard-and-fast instruction here: If an immediate plant shutdown is required to provide adequate protection of the public, do not let LIC-504 get in the way of taking necessary action. The other parts of the figure provide guidance; judgment should be exercised. For example, an issue may have a communication plan, but still hinge on only one driving factor, making the standard option a likely choice. As another example, an issue may be complex, need a great deal of deliberation, and otherwise indicate the detailed approach, but there may not be adequate time to implement that approach. The standard approach can be used in such cases. If circumstances warrant, the team can switch over to the detailed approach to bolster its analysis or conclusions.

Obvious Need to Shutdown Plant

- If it is obvious up-front that a plant shutdown is required, do not enter LIC-504*
- If in LIC-504 and it is determined that an immediate shutdown of a plant is required:
 - Enter LIC 106 or the NRC Enforcement Manual process
 - Do not let LIC-504 processes interfere with taking necessary and timely action
 - LIC 504 may be suspended or curtailed at that time by cognizant management
- * Unless management opts to use LIC-504 to supplement the other process

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Already discussed in the speaker's notes for the previous slide. This is an important point.

Covered by other NRC Process

- If an issue is covered by another NRC process, do not enter LIC-504 ...
- ... Unless management opts to use LIC-504 to supplement the other process:
 - To provide structured decision-making process
 - To provide structured documentation of decision

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Once again, LIC-504 is not intended to replace or supersede other processes or procedures. Management may opt to use LIC-504 to supplement other process if warranted for a given issue.

Clearly Low Safety Significance

- If it is clearly concluded that the safety concern can be considered of low significance, exit LIC-504
- It should be clear that the risk impact is very small; e.g.
 - $\Delta\text{CCDF} < 1 \times 10^{-7}$ per reactor year
 - Minimal degradation of defense-in-depth or safety margin
- All five key principles of risk-informed regulation* should be considered to the extent warranted
- The information and/or analyses used to conclude “low safety significance” should be documented and communicated (good opportunity to use Appendix B of LIC-504, “standard approach”)

*Refer to supplementary material near end of this slide presentation for the 5 key principles

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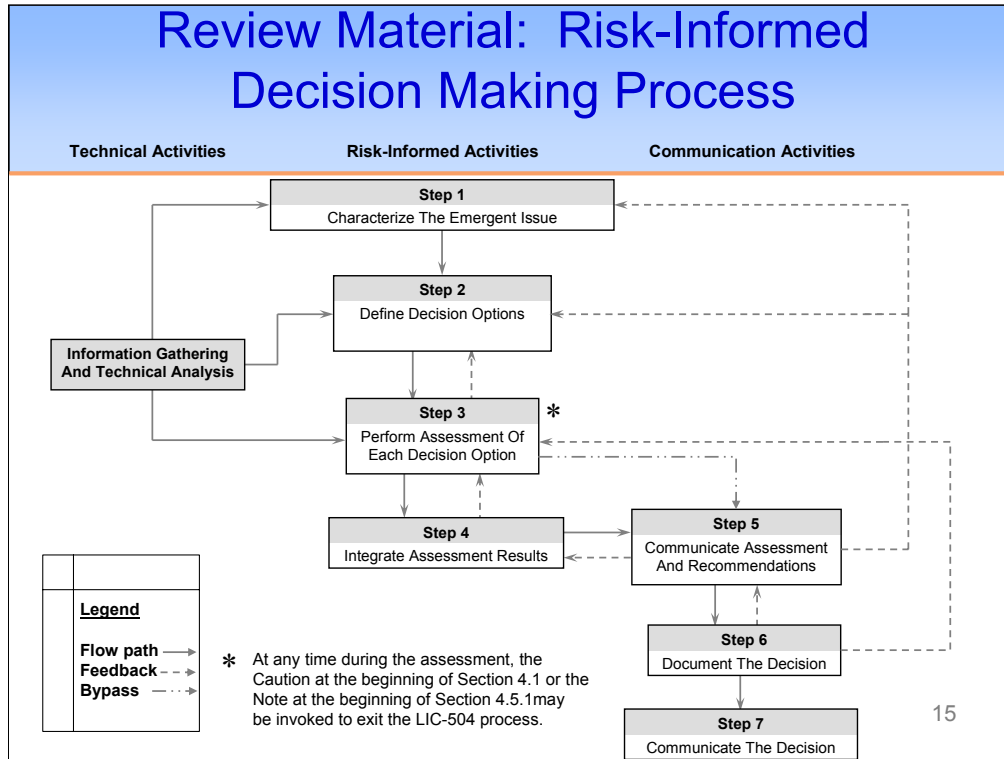
It is possible that LIC-504 would be entered and, only after some amount of analysis, it would be concluded that the issue was of low safety significance. Whenever such a conclusion is arrived at, LIC-504 allows you to exit. However, it is a good idea to document the basis for such a conclusion, especially if it was not “obvious to the casual observer!”

Which Approach to Use?

- Standard Approach
 - Options to resolve issue are clear
 - One or maybe two factors influence choice of option to resolve issue
- Detailed Approach
 - Issue requires highly deliberative decision process
 - Issue needs a structured assessment of risk, defense-in-depth, safety margins, and possibly other RG 1.174 factors
- Both approaches use same basic framework for thinking about an issue and documenting the decision
- May switch from standard to detailed (or vice versa) as more information arises regarding the issue

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Either approach uses the same decision making process, and the analyst is not bound by the initial decision of which approach to use – switching between approaches is fine. In fact, even for the standard approach, a team may consult the detailed approach attachments to help focus thoughts on one or more of the key principles of risk-informed regulation.



The decision process is generic – figure out what the issue is, develop options to address the issue, find a way to evaluate the options against criteria, make a decision, and tell affected parties what the decision is. LIC-504 stresses the need to document the decision, including the basis, to provide scrutability.

Note the feedback paths – the process is highly iterative. As the process proceeds, new information may result in the need to go back to a previous step (for example).

Step 1 – Characterize the Issue

- Characterize the issue in terms of the physical impact on the plant and the potential impact on safe operation, well enough to:
 - Make initial assessment of those organizations that must be involved
 - Determine what information will be needed to perform subsequent steps
 - Consider any sources of information that may provide useful information on the issue:
 - UFSAR and Safety Evaluation Report
 - Inspection reports
 - Results of team inspections
 - Incident reports

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This step is to figure out what the issue is, and gather information necessary to proceed to the next steps in the process. Remember that the process is iterative, such that information gathering may proceed throughout the process. As subsequent steps are started, different aspects of the issue may become clear, or the need for additional information may become manifest.

Step 2 – Define Decision Options

- Determine decision environment: Urgency, available tools, resources
- Define the decision options to resolve the issue; e.g.:
 - Immediate plant shut down
 - Shut the plant down within a specified time period
 - Continued operation with the implementation of compensatory actions
 - Delay the decision until more information is available.
- Describe the guidelines or criteria for acceptability or rejection of each decision option
- Describe the factors that determine the approach to the analysis of the issue and the selection of options
- Identify the potential primary decision makers
- NOTE: Choice of options may change as more information becomes available. Process is iterative to allowing adjustments to the original scope or approach.

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There are almost always two major options: maintain conditions as they are (status quo), or require some change. The options could be to increase a surveillance frequency, or institute condition monitoring, or operate at reduced power (de-rate the unit), or to shut down the plant. There is no specified number of options that need be considered. Each option developed in this stage will be subject to an analysis, so it is a good practice to limit the options to those that cover a range of likely decision choices.

Step 3 – Assess Each Option

- Analyze and document the assessment of each option
 - Determine factors that differentiate among options
 - e.g., 5 key principles of risk-informed regulation
 - Other factors that will drive the decision
 - Assess each option in terms of how each factor is affected
 - Assess the technical adequacy of each analytical method used
- Document the analysis of each input to the decision in a similar manner:
 - 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

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In the standard approach, there may only be one or a couple of factors that will differentiate between the options. In the detailed approach, all 5 key principles would usually be addressed, as well as any other factors relevant to the decision.

The second major bullet points out that not only the analysis results are important to the decision. It is also necessary to understand the assumptions, uncertainties, and degree of confidence in the conclusions.

Step 4 – Integrate Assessment Results

- Summarize the results for each decision option
 - The driving factors for the assessment of the option. Driving factors are those that play the most significant role in the decision (e.g., defense in depth, safety margin, risk, etc.).
 - Key technical inputs. A key technical input is an essential input to the analysis that enables the conclusion of acceptability or non-acceptability
 - Assessment of the validity and applicability of each technical input
 - Assessment of the confidence in the assessment, recognizing the uncertainties in the technical inputs
- Determine the preferred option – the decision that the technical team is recommending to the decision authority!

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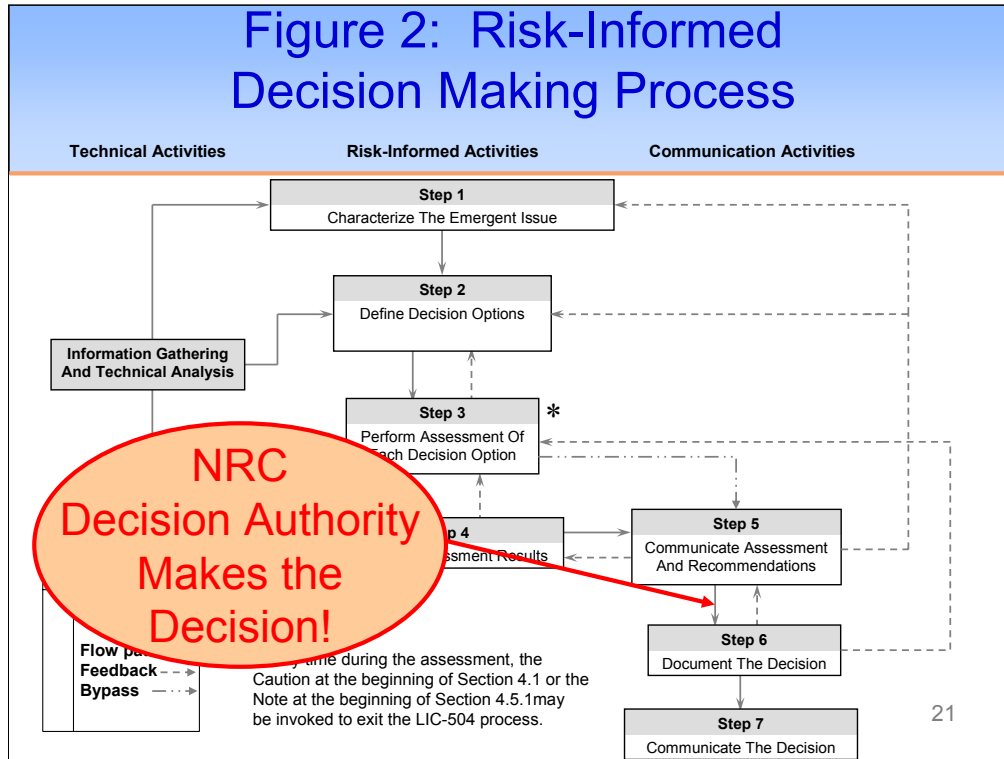
If this were a numerical “multi-attribute decision theory” approach, this is where the “weights” of each attribute would be combined by the “score” that attribute received to provide a numerical rank for each option. In LIC-504, the attributes are referred to as factors. A numerical algorithm is not provided, because judgment is required to weigh not only the factors, but also the uncertainty and degree of confidence in the assessment. LIC-504, Attachment C-2 to Appendix C, “Reaching Consensus on a Recommendation,” provides some guidance on how to integrate the assessment results when a team approach is used.

Step 5 – Communicate Assessment and Recommendation

- Purpose – provide decision maker the information needed to make properly informed decision
- Suggested content (may be formal or informal):
 - Background: Sufficient information on the issue and the decision to be made
 - Decision: State the decision that is required clearly and concisely
 - Options: Present individually and concisely
 - Present driving factors for accepting or rejecting each option, including uncertainties
 - Document the logical basis for accepting/rejecting each option
 - Recommendation: Summarize the logic for the recommended option
 - Supporting Details: Provide qualitative insight into causes, uncertainties, assumptions, sensitivities and affected outcomes for a given situation
 - Other relevant information: (e.g., generic implications, stakeholder concerns)

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The recommended option is provided to the decision maker, along with enough information to make an informed decision. This information includes the options that were considered, the analysis of the driving factors (including assumptions, uncertainty, confidence), and why the recommended option was considered the most appropriate.



This slide shows that LIC-504 is a decision-making process, but is not intended to teach managers how to make a decision. The process flow chart does not have a step “make the decision,” which obviously must take place between steps 5 and 6.

Step 6 – Document the Decision

- Once the decision has been made, the staff should document the decision consistent with its importance
- Documentation of the decision should include:
 - What decision was made
 - 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

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Document the decision – the slide is self-explanatory.

Step 7 – Communicate the Decision

- The decision and related information should be communicated to the various stakeholders
- If a Communication Plan was developed, communicate per the plan
- Information to communicate may include:
 - Issue background
 - Options considered
 - Decision that was made
 - Rationale for the chosen option
 - Impact of the decision on stakeholders

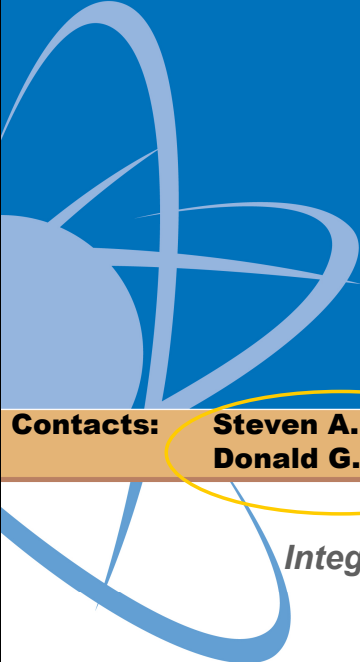
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The level and form of communication should be commensurate with the issue and stakeholder interest, to mention two factors.

Summary

- LIC-504, Revision 3
 - Provides better entry guidance
 - Includes two approaches, Standard and Detailed
- LIC-504 process should be entered when:
 - Potentially risk-significant emergent issues are involved
 - Significant concerns about safety margin or defense in depth exist
 - Other risk-informed processes call for increased management attention
- Figure 1 of LIC-504 guides entry into the process
 - Three screening questions (may opt out of LIC-504)
 - Obvious need to immediately shutdown a plant
 - Issue comes under another NRC process
 - Issue is clearly low safety significance
 - Decision box to help determine which approach to use

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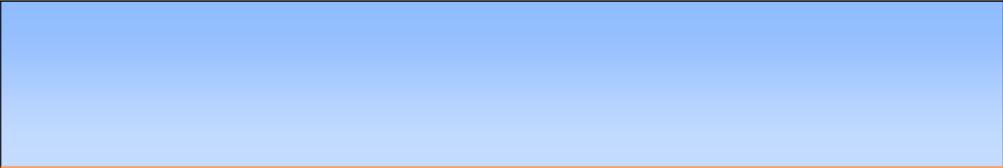
**Questions on
NRR Office Instruction
LIC-504 Revision 3?**

Ask the Contacts!

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

This ends the self-study for LIC-504 Revision 3. Proceed further if interested in (1) why LIC-504 was written or (2) the 5 key principles of risk-informed regulation.



**SUPPLEMENTARY INFORMATION:
WHY LIC-504?**

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Why LIC-504?

- LIC-504 resulted from GAO audit* after Davis Besse reactor vessel head degradation
- GAO recommendation that led to LIC-504:
 - Improve the NRC's use of 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
 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

* 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

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The GAO report had 5 recommendations. LIC-504 was written to address 2 of them: the one shown on the slide, and another having to do with developing guidance for when to shut down a reactor. The answer to the second recommendation was "NRC already has such guidance" and LIC-504 refers the user to LIC-506 or the NRC Enforcement Manual.

Why LIC-504?

- LIC-504 developed to address the GAO recommendation
- However, 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.

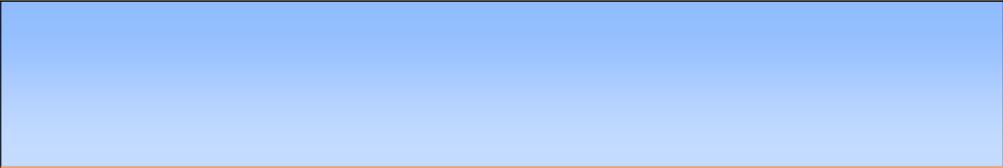
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Once again, documentation of how and why a decision was made allows subsequent auditors to judge how well we did.

Why LIC-504?

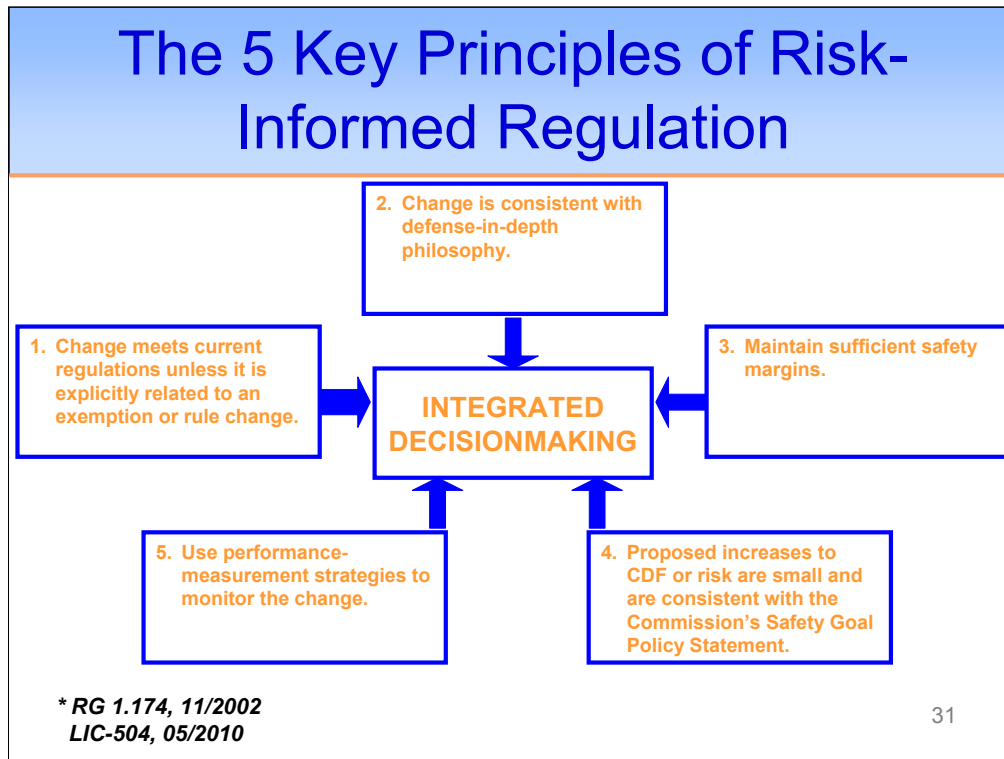
- Objective of LIC-504
 - To outline a process for the development and documentation of risk-informed decisions
- Applicability
 - Reactor-based, risk-informed decision-making not already covered by established processes
 - However, the basic steps can apply to other risk-informed applications
 - Not intended to replace existing risk-informed decision-making processes (e.g., Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,"
 - Can be used to supplement to existing risk-informed processes

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**SUPPLEMENTAL INFORMATION:
FIVE KEY PRINCIPLES OF
RISK-INFORMED REGULATION**

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Five principles established in RG 1.174, the first really explicit PRA-informed regulatory guide

The first three principles are evaluated by DESIGN BASIS reviewers, not risk analysts – every decision includes BOTH components.

Performance monitoring is the safety net to ensure that important factors and assumptions in the determination of technical adequacy remain true.

Conformance with regulations – self explanatory. Remaining 4 principles are covered on subsequent slides.

Defense-in-Depth

- Consistency with defense-in-depth philosophy is maintained if:
 - A reasonable balance is preserved among prevention of core damage, prevention of containment failure, and consequence mitigation.
 - Over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided.
 - System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).
 - Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed.
 - Independence of barriers is not degraded.
 - Defenses against human errors are preserved.
 - The intent of the General Design Criteria in Appendix A to 10 CFR Part 50 is maintained.

Source: RG 1.174, 11/2002

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It is difficult to define “defense-in-depth,” but RG 1.174 provides the attributes that indicate when consistency with the DID philosophy is maintained.

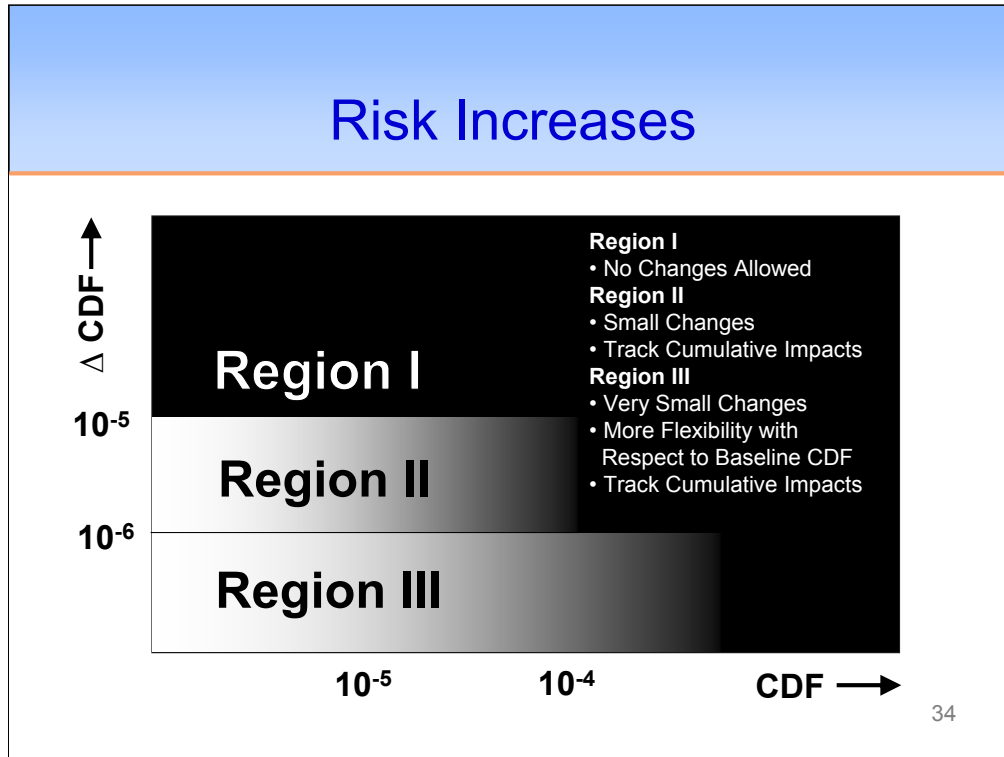
Safety Margins

- With sufficient safety margins:
 - Codes and standards or their alternatives approved for use by the NRC are met.
 - Safety analysis acceptance criteria in the LB (e.g., FSAR, supporting analyses) are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

Source: RG 1.174, 11/2002

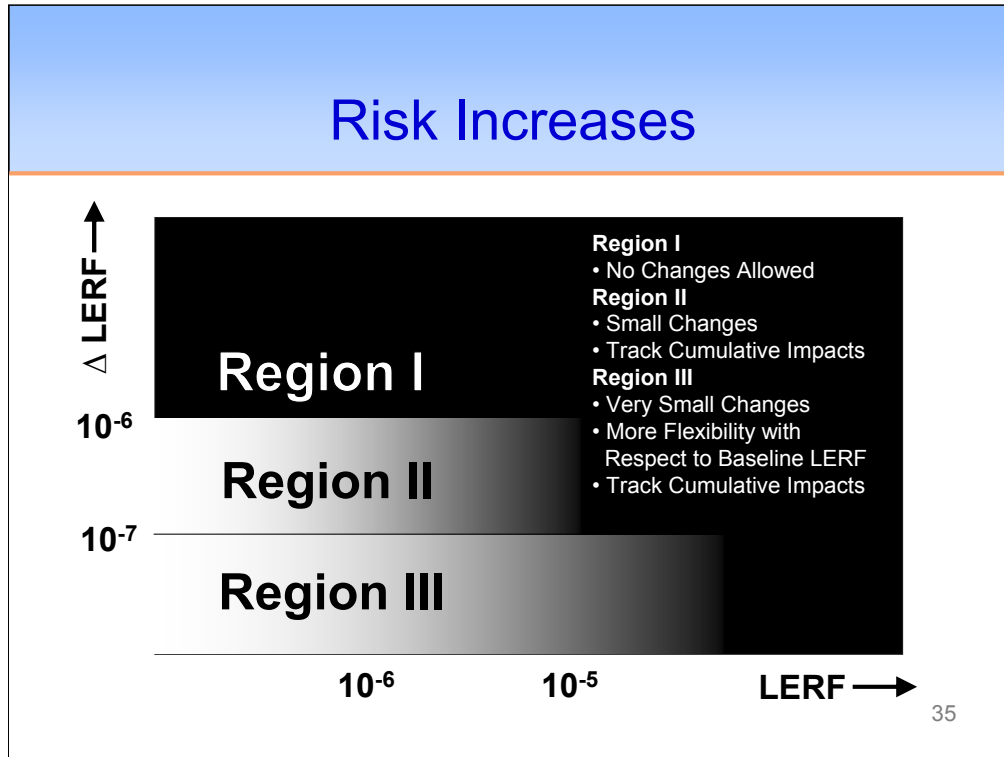
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Similar to DID, RG 1.174 provides an indication of when sufficient safety margins exist without defining “safety margin.”



This slide for core damage frequency [CDF] shows the risk acceptance guidelines from RG 1.174. If the change in risk is in Region II or Region III, it is considered “small and consistent with the intent of the Commission's Safety Goal Policy Statement.” Total plant risk (not limited to internal events, but including fire, seismic, etc.) is the x-axis; the risk increase (delta core CDF) is on the y-axis.

Note the fuzzy boundaries on the right side of Regions II and III – this is intentional. The total plant risk acceptance guideline is not hard and fast – changes that will increase risk a little above $1\text{E-}4$ (CDF) may be acceptable if the risk increase is “small” or “very small.”



This slide for large early release frequency [LERF] shows the risk acceptance guidelines from RG 1.174. Same comments as preceding slide. Note that the acceptance guidelines are 1 order of magnitude below the corresponding ones for CDF (both axes).

Performance Measurement

- In risk-informed licensing actions, the primary goal for performance monitoring strategies is to ensure that no adverse safety degradation occurs because of the changes to the licensing basis
 - Possibility that the aggregate impact of changes that affect a large class of SSCs could lead to an unacceptable increase in the number of failures from unanticipated degradation, including possible increases in common cause mechanisms
 - Implementation and monitoring plan to ensure that the conclusions that have been drawn from the engineering evaluation remain valid (continues to reflect the actual reliability and availability of SSCs that were evaluated)

Source: RG 1.174, 11/2002

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When granting licensing basis changes, we require licensees to monitor the effects of the change to ensure there are no unintended, adverse consequences. For decision-making regarding emergent issues, this key principle might take the form of compensatory measures to help detect any further degradation (for example) or to mitigate an actual failure.