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# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 1.174

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# AN APPROACH FOR USING PROBABILISTIC RISK ASSESSMENT IN RISK-INFORMED DECISIONS ON PLANT-SPECIFIC CHANGES TO THE LICENSING BASIS

## 1. PURPOSE AND SCOPE

### 1.1 INTRODUCTION

The NRC's policy statement on probabilistic risk assessment (PRA) (Ref. 1) encourages greater use of this analysis technique to improve safety decisionmaking and improve regulatory efficiency. The NRC staff's Risk-Informed Regulation Implementation Plan (Ref. 2) describes activities now under way or planned to expand this use. These activities include, for example, providing guidance for NRC inspectors on focusing inspection resources on risk-important equipment.

Another activity under way in response to the policy statement is using PRA to support decisions to modify an individual plant's licensing basis (LB).[1] This regulatory guide provides guidance on the use of PRA findings and risk insights in support of licensee requests for changes to a plant's LB, as in requests for license amendments and technical specification changes under Sections 50.90-92 of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." It does not address licensee-initiated changes to the LB that do NOT require NRC review and approval (e.g., changes to the facility as described in the final safety analysis report (FSAR), the subject of 10 CFR 50.59).

Licensee-initiated LB changes that are consistent with currently approved staff positions (e.g., regulatory guides, standard review plans, branch technical positions, or the Standard

[1] These are modifications to a plant's design, operation, or other activities that require NRC approval. These modifications could include items such as exemption requests under 10 CFR 50.11 and license amendments under 10 CFR 50.90.

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Technical Specifications) are normally evaluated by the staff using traditional engineering analyses. A licensee generally would not be expected to submit risk information in support of the proposed change.

Licensee-initiated LB change requests that go beyond current staff positions may be evaluated by the staff using traditional engineering analyses as well as the risk-informed approach set forth in this regulatory guide. A licensee may be requested to submit supplemental risk information if such information is not submitted by the licensee. If risk information on the proposed LB change is not provided to the staff, the staff will review the information provided by the licensee to determine whether the application can be approved. Based on the information provided, using traditional methods, the NRC staff will either approve or reject the application.

However, licensees should be aware that special circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as the identification of an issue related to the requested LB change that may substantially increase risk. In such circumstances, the NRC has the statutory authority to require licensee action above and beyond existing regulations and may request an analysis of the change in risk related to the requested LB change to demonstrate that the level of protection necessary to avoid undue risk to public health and safety (i.e., "adequate protection") would be maintained upon approval of the requested LB change.

This regulatory guide describes an acceptable method for the licensee and NRC staff to use in assessing the nature and impact of LB changes when the licensee chooses to support or is requested by the staff to support the changes with risk information. The NRC staff would review these LB changes by considering engineering issues and applying risk insights. Licensees who submit risk information (whether on their own initiative or at the request of the staff) should address each of the principles of risk-informed regulation discussed in this regulatory guide. Licensees should identify how their chosen approaches and methods (whether quantitative or qualitative, deterministic or probabilistic), data, and criteria for considering risk are appropriate for the decision to be made.

Additional guidance is provided to the NRC staff (in Appendix D to Chapter 19 of the Standard Review Plan, Ref. 3) regarding the circumstances and process under which NRC staff reviewers would request and use risk information in the review of non-risk-informed license amendment requests.

The guidance provided in this regulatory guide does not preclude other approaches for requesting changes to the LB. Rather, this regulatory guide is intended to improve consistency in regulatory decisions in areas in which the results of risk analyses are used to help justify regulatory action. As such, the principles, process, and approach discussed herein also provide useful guidance for the application of risk information to a broader set of activities than plant-specific changes to a plant's LB (i.e., generic activities), and licensees are encouraged to use this guidance in that regard.

## 1.2 BACKGROUND

During the last several years, both the NRC and the nuclear industry have recognized that PRA has evolved to the point that it can be used increasingly as a tool in regulatory decisionmaking. In August 1995, the NRC adopted the following policy statement (Ref. 1) regarding the expanded use of PRA.

- The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state of the art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

- PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on need for proposing and backfitting new generic requirements on nuclear power plant licensees.

In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: foremost, through safety decisionmaking enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees.

In parallel with the publication of the policy statement, the staff developed an implementation plan to define and organize the PRA-related activities being undertaken (Ref. 2). These activities cover a wide range of PRA applications and involve the use of a variety of PRA methods (with variety including both types of models used and the detail of modeling needed). For example, one application involves the use of PRA in the assessment of operational events in reactors. The characteristics of these assessments permit relatively simple PRA models to be used. In contrast, other applications require the use of detailed models.

The activities described in the PRA Implementation Plan (Ref. 2) with its updates relate to a number of agency interactions with the regulated industry. With respect to reactor regulation, activities include, for example, developing guidance for NRC inspectors on focusing inspection resources on risk-important equipment and reassessing plants with relatively high core-damage frequencies (CDF) for possible backfit.

This regulatory guide focuses on the use of PRA in a subset of the applications described in the staff's implementation plan. Its principal focus is the use of PRA findings and risk insights in decisions on proposed changes to a plant's LB.

This regulatory guide also makes use of the NRC's Safety Goal Policy Statement (Ref. 4). As discussed below, one key principle in risk-informed regulation is that proposed increases in CDF and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. The safety goals (and associated quantitative health objectives (QHOs)) define an acceptable level of risk that is a small fraction (0.1%) of other risks to which the public is exposed. The acceptance guidelines defined in this regulatory guide (in Section 2.2.4) are based on subsidiary objectives derived from the safety goals and their QHOs.

## 1.3 PURPOSE OF THIS REGULATORY GUIDE

Changes to many of the activities and design characteristics in a nuclear power plant's LB require NRC review and approval. This regulatory guide provides the staff's recommendations for using risk information in support of licensee-initiated LB changes to a nuclear power plant that require such review and approval. The guidance provided here does not preclude other approaches for requesting LB changes. Rather, this regulatory guide is intended to improve consistency in regulatory decisions in areas in which the results of risk analyses are used to help justify regulatory action. As such, this regulatory guide, the use of which is voluntary, provides general guidance concerning one approach that the NRC has determined to be acceptable for analyzing issues associated with proposed changes to a plant's LB and for assessing the impact of such proposed changes on the risk associated with plant design and operation. This guidance does not address the specific analyses needed for each nuclear power plant activity or design characteristic that may be amenable to risk-informed regulation.

## 1.4 SCOPE OF THIS REGULATORY GUIDE

This regulatory guide describes an acceptable approach for assessing the nature and impact of proposed LB changes by considering engineering issues and applying risk insights.

Assessments should consider relevant safety margins and defense-in-depth attributes, including consideration of success criteria as well as equipment functionality, reliability, and availability. The analyses should reflect the actual design, construction, and operational practices of the plant. Acceptance guidelines for evaluating the results of such assessments are provided. This guide also addresses implementation strategies and performance monitoring plans associated with LB changes that will help ensure that assumptions and analyses supporting the change are verified.

Consideration of the Commission's Safety Goal Policy Statement (Ref. 4) is an important element in regulatory decisionmaking. Consequently, this regulatory guide provides acceptance guidelines consistent with this policy statement.

In theory, one could construct a more generous regulatory framework for consideration of those risk-informed changes that may have the effect of increasing risk to the public. Such a framework would include, of course, assurance of continued adequate protection (that level of protection of the public health and safety that must be reasonably assured regardless of economic cost). But it could also include provision for possible elimination of all measures not needed for adequate protection, which either do not effect a substantial reduction in overall risk or result in continuing costs that are not justified by the safety benefits. Instead, in this regulatory guide, the NRC has chosen a more restrictive policy that would permit only small increases in risk, and then only when it is reasonably assured, among other things, that sufficient defense in depth and sufficient margins are maintained. This policy is adopted because of uncertainties and to account for the fact that safety issues continue to emerge regarding design, construction, and operational matters notwithstanding the maturity of the nuclear power industry. These factors suggest that nuclear power reactors should operate routinely only at a prudent margin above adequate protection. The safety goal subsidiary objectives are used as an example of such a prudent margin.

Finally, this regulatory guide indicates an acceptable level of documentation that will enable the staff to reach a finding that the licensee has performed a sufficiently complete and scrutable analysis and that the results of the engineering evaluations support the licensee's request for a regulatory change.

## 1.5 RELATIONSHIP TO OTHER GUIDANCE DOCUMENTS

Directly relevant to this regulatory guide is the Standard Review Plan (SRP) designed to guide the NRC staff evaluations of licensee requests for changes to the LB that apply risk insights (Ref. 3), as well as guidance that is being developed in selected application-specific regulatory guides and the corresponding standard review plan chapters. Related regulatory guides have been developed on inservice testing, inservice inspection, graded quality assurance, and technical specifications (Refs. 5-8). An NRC contractor report (Ref. 9) is also available that provides a simple screening method for assessing one measure used in the regulatory guide—large early release frequency. The staff recognizes that the risk analyses necessary to support regulatory decisionmaking may vary with the relative weight that is given to the risk assessment element of the decisionmaking process. The burden is on the licensee who requests a change to the LB to justify that the chosen risk assessment approach, methods, and data are appropriate for the decision to be made.

The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget (OMB), approval number 3150-3011. The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requested document displays a currently valid OMB control number.

## 2. AN ACCEPTABLE APPROACH TO RISK-INFORMED DECISIONMAKING

In its approval of the policy statement on the use of PRA methods in nuclear regulatory activities (Ref. 1), the Commission stated an expectation that "the use of PRA technology should be increased in all regulatory matters . . . in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." The use of risk insights in licensee submittals requesting LB changes will assist the staff in the disposition of such licensee proposals.

The staff has defined an acceptable approach to analyzing and evaluating proposed LB changes. This approach supports the NRC's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from the use of PRA methods) about the risk significance of the proposed changes. Decisions concerning proposed changes are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information.

In implementing risk-informed decisionmaking, LB changes are expected to meet a set of key principles. Some of these principles are written in terms typically used in traditional engineering decisions (e.g., defense in depth). While written in these terms, it should be understood that risk analysis techniques can be, and are encouraged to be, used to help ensure and show that these principles are met. These principles are:

1. The proposed change meets the current regulations unless it is explicitly related to a requested exemption or rule change, i.e., a "specific exemption" under 10 CFR 50.12 or a "petition for rulemaking" under 10 CFR 2.802.

2. The proposed change is consistent with the defense-in-depth philosophy.

3. The proposed change maintains sufficient safety margins.

4. When proposed changes result in an increase in core damage frequency or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement (Ref. 5).[2]

5. The impact of the proposed change should be monitored using performance measurement strategies.

Each of these principles should be considered in the risk-informed, integrated decisionmaking process, as illustrated in Figure 1.

[2] For purposes of this guide, a proposed LB change that meets the acceptance guidelines discussed in Section 2.2.4 is considered to have met the intent of the policy statement.

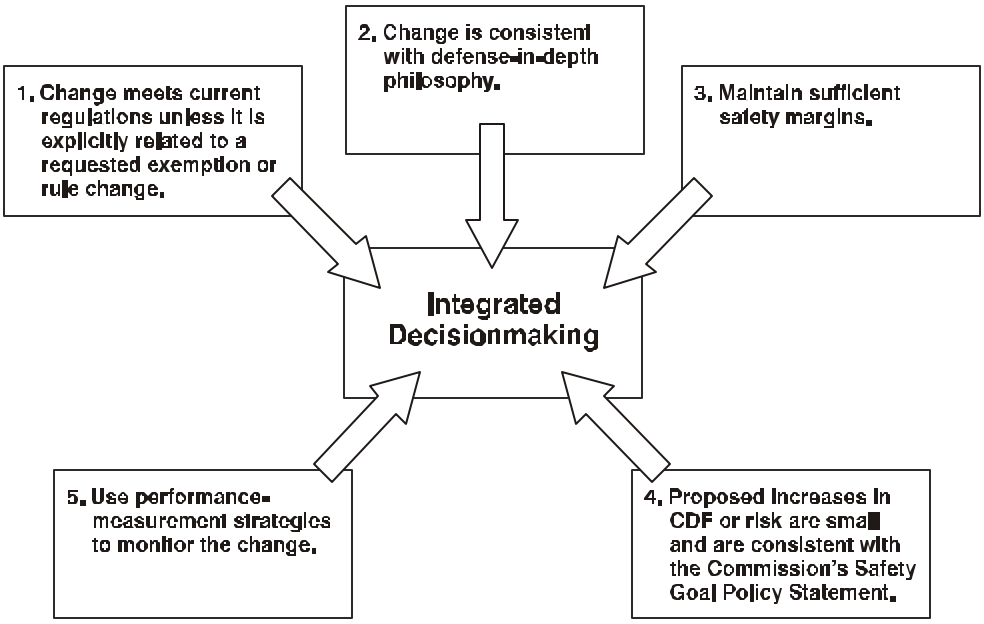


**Figure 1. Principles of Risk-Informed Integrated Decisionmaking**

The staff's proposed evaluation approach and acceptance guidelines follow from these principles. In implementing these principles, the staff expects that:

- All safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly by identifying and taking advantage of opportunities to reduce risk, and not just to eliminate requirements the licensee sees as undesirable. For those cases when risk increases are proposed, the benefits should be described and should be commensurate with the proposed risk increases. The approach used to identify changes in requirements should be used to identify areas where requirements should be increased as well as where they can be reduced.

- The scope, level of detail, and technical acceptability of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed LB change should be appropriate for the nature and scope of the change, should be based on the as-built and as-operated and maintained plant, and should reflect operating experience at the plant.

- The plant-specific PRA supporting the licensee's proposals has been subjected to quality assurance methods and quality control methods.

- Appropriate consideration of uncertainty is given in analyses and interpretation of findings, including using a program of monitoring, feedback, and corrective action to address significant uncertainties.

- The use of core damage frequency (CDF) and large early-release frequency (LERF)[3] as bases for PRA acceptance guidelines is an acceptable approach to addressing Principle 4. Use of the Commission's Safety Goal QHOs in lieu of LERF is acceptable in principle, and licensees may propose their use. However, in practice, implementing such an approach would require an extension to a Level 3 PRA, in which case the methods and assumptions used in the Level 3 analysis, and associated uncertainties, would require additional attention.

- Increases in estimated CDF and LERF resulting from proposed LB changes will be limited to small increments. The cumulative effect of such changes should be tracked and considered in the decision process.

- The acceptability of proposed changes should be evaluated by the licensee in an integrated fashion that ensures that all principles are met.

- Data, methods, and assessment criteria used to support regulatory decisionmaking must be well documented and available for public review.

Given the principles of risk-informed decisionmaking discussed above, the staff has identified a four-element approach to evaluating proposed LB changes. This approach, which is presented graphically in Figure 2, acceptably supports the NRC's decisionmaking process. This approach is not sequential in nature; rather it is iterative.

## 2.1 ELEMENT 1: DEFINE THE PROPOSED CHANGE

Element 1 involves three primary activities. First, the licensee should identify those aspects of the plant's LB that may be affected by the proposed change, including but not limited to rules and regulations, final safety analysis report (FSAR), technical specifications, licensing conditions, and licensing commitments. Second, the licensee should identify all structures, systems, and components (SSCs), procedures, and activities that are covered by the LB change being evaluated and should consider the original reasons for including each program requirement.

When considering LB changes, a licensee may identify regulatory requirements or commitments in its LB that it believes are overly restrictive or unnecessary to ensure safety at the plant. Note that the corollary is also true; that is, licensees are also expected to identify design and operational aspects of the plant that should be enhanced consistent with an improved understanding of their safety significance. Such enhancements should be embodied in appropriate LB changes that reflect these enhancements.

[3] In this context, LERF is being used as a surrogate for the early fatality QHO. It is defined as the frequency of those accidents leading to significant, unmitigated releases from containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure at or shortly after vessel breach, containment bypass events, and loss of containment isolation. This definition is consistent with accident analyses used in the safety goal screening criteria discussed in the Commission's regulatory analysis guidelines. An NRC contractor's report (Ref. 10) describes a simple screening approach for calculating LERF.

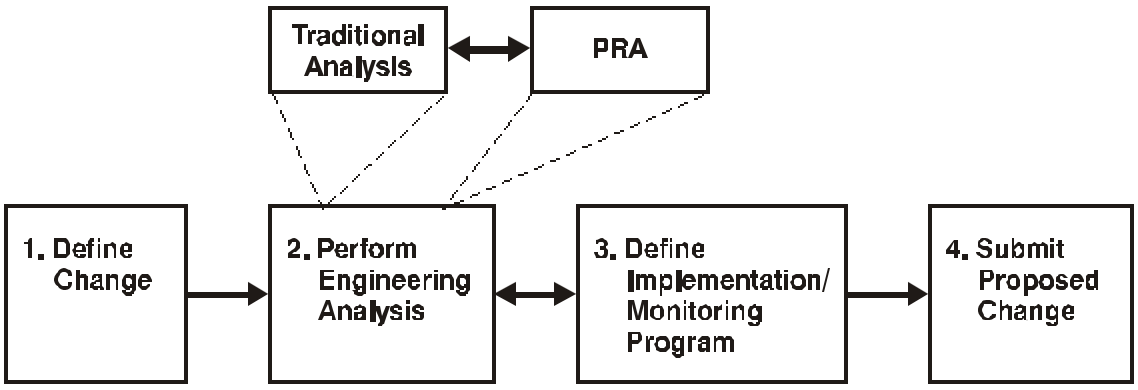


**Figure 2. Principal Elements of Risk-Informed, Plant-Specific Decisionmaking**

Third, with this staff expectation in mind, the licensee should identify available engineering studies, methods, codes, applicable plant-specific and industry data and operational experience, PRA findings, and research and analysis results relevant to the proposed LB change. With particular regard to the plant-specific PRA, the licensee should assess the capability to use, refine, augment, and update system models as needed to support a risk assessment of the proposed LB change.

The above information should be used collectively to describe the LB change and to outline the method of analysis. The licensee should describe the proposed change and how it meets the objectives of the NRC's PRA Policy Statement (Ref. 1), including enhanced decisionmaking, more efficient use of resources, and reduction of unnecessary burden. In addition to improvements in reactor safety, this assessment may consider benefits from the LB change such as reduced fiscal and personnel resources and radiation exposure. The licensee should affirm that the proposed LB change meets the current regulations unless the proposed change is explicitly related to a proposed exemption or rule change (i.e., a "specific exemption" under 10 CFR 50.12 or a "petition for rulemaking" under 10 CFR 2.802).

### 2.1.1 Combined Change Requests

Licensee proposals may include several individual changes to the LB that have been evaluated and will be implemented in an integrated fashion. The staff expects that, with respect to the overall net change in risk, combined change requests (CCRs) will fall in one of two broad categories, each of which may be acceptable:

1. CCRs in which any individual change increases risk;

2. CCRs in which each individual change decreases risk.

In the first category, the contribution of each individual change in the CCR must be quantified in the risk assessment and the uncertainty of each individual change must be addressed. For CCRs in the second category, qualitative analysis may be sufficient for some or all individual changes. Guidelines for use in developing CCRs are discussed below.

### 2.1.2 Guidelines for Developing CCRs

The changes that make up a CCR should be related to one another, for example, by affecting the same single system or activity, by affecting the same safety function or accident sequence or group of sequences, or by being of the same type (e.g., changes in outage time allowed by technical specifications). However, this does not preclude acceptance of unrelated changes. When CCRs are submitted to the NRC staff for review, the relationships among the individual changes and how they have been modeled in the risk assessment should be addressed in detail, since this will control the characterization of the net result of the changes. Licensees should evaluate not only the individual changes but also the changes taken together against the safety principles and qualitative acceptance guidelines in Sections 2 and 2.2.1, respectively, of this regulatory guide. In addition, the acceptability of the cumulative impact of the changes that make up the CCR with respect to the quantitative acceptance guidelines discussed in Section 2.2.4 of this guide should be assessed.

In implementing CCRs in the first category, it is expected that the risk from significant accident sequences will not be increased and that the frequencies of the lower ranked contributors will not be increased so that they become significant contributors to risk. It is expected that no significant new sequences or cutsets will be created. In assessing the acceptability of CCRs, (1) risk increases related to the more likely initiating events (e.g., steam generator tube ruptures) should not be traded against improvements related to unlikely events (e.g., earthquakes) even if, for instance, they involve the same safety function, and (2) risk should be considered in addition to likelihood. The staff also expects that CCRs will lead to safety benefits such as simplifying plant operations or focusing resources on the most important safety items.

Proposed changes that modify one or more individual components of a previously approved CCR must also address the impact on the previously approved CCR. Specifically, the question to be addressed is whether the proposed modification would cause the previously approved CCR to not be acceptable. If the answer is yes, the submittal should address the actions the licensee is taking with respect to the previously approved CCR.

## 2.2 ELEMENT 2: PERFORM ENGINEERING ANALYSIS

The staff expects that the scope, level of detail, and technical acceptability of the engineering analyses conducted to justify the proposed LB change will be appropriate for the nature and scope of the change. The staff also expects that appropriate consideration will be given to uncertainty in the analysis and interpretation of findings. The licensee is expected to use judgment on the complexity and difficulty of implementing the proposed LB change to decide upon appropriate engineering analyses to support regulatory decisionmaking. Thus, the licensee should consider the appropriateness of qualitative and quantitative analyses, as well as analyses using traditional engineering approaches and those techniques associated with the use of PRA findings. Regardless of the analysis methods chosen, the licensee must show that the principles set forth in Section 2 have been met through the use of scrutable acceptance guidelines established for making that determination.

Some proposed LB changes can be characterized as involving the categorization of SSCs according to safety significance. An example is grading the application of quality assurance controls commensurate with the safety significance of equipment. Like other applications, the staff's review of LB change requests for applications involving safety categorization will be according to the acceptance guidelines associated with each key principle presented in this regulatory guide, unless equivalent guidelines are proposed by the licensee. Since risk-importance measures are often used in such categorizations, guidance on their use is provided in Appendix A to this regulatory guide. Other application-specific guidance documents address guidelines associated with the adequacy of programs (in this example, quality controls) implemented for different safety-significant categories (e.g., more safety significant and less safety significant). Licensees are encouraged to apply risk-informed findings and insights to decisions (and potential LB requests).

As part of the second element, the licensee will evaluate the proposed LB change with regard to the principles that adequate defense-in-depth is maintained, that sufficient safety margins are maintained, and that proposed increases in CDF and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement.

### 2.2.1 Evaluation of Defense-in-Depth Attributes and Safety Margins

One aspect of the engineering evaluations is to show that the fundamental safety principles on which the plant design was based are not compromised. Design basis accidents (DBAs) play a central role in nuclear power plant design. DBAs are a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response. During the design process, plant response and associated safety margins are evaluated using assumptions that are intended to be conservative. National standards and other considerations such as defense-in-depth attributes and the single failure criterion constitute additional engineering considerations that influence plant design and operation. Margins and defenses associated with these considerations may be affected by the licensee's proposed LB change and, therefore, should be reevaluated to support a requested LB change. As part of this evaluation, the impact of the proposed LB change on affected equipment functionality, reliability, and availability should be determined.

#### 2.2.1.1 Defense in Depth

The engineering evaluation should evaluate whether the impact of the proposed LB change (individually and cumulatively) is consistent with the defense-in-depth philosophy. In this regard, the intent of the principle is to ensure that the philosophy of defense in depth is maintained, not to prevent changes in the way defense in depth is achieved. The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance. If a comprehensive risk analysis is done, it can be used to help determine the appropriate extent of defense in depth (e.g., balance among core damage prevention, containment failure, and consequence mitigation) to ensure protection of public health and safety. When a comprehensive risk analysis is not or cannot be done, traditional defense-in-depth considerations should be used or maintained to account for uncertainties. The evaluation should consider the intent of the

general design criteria, national standards, and engineering principles such as the single failure criterion. Further, the evaluation should consider the impact of the proposed LB change on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes. As stated earlier, the licensee should select the engineering analysis techniques, whether quantitative or qualitative, traditional or probabilistic, appropriate to the proposed LB change.

The licensee should assess whether the proposed LB change meets the defense-in-depth principle. Defense in depth consists of a number of elements, as summarized below. These elements can be used as guidelines for making that assessment. Other equivalent acceptance guidelines may also be used.

Consistency with the 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.

**2.2.1.2 Safety Margins**

The engineering evaluation should assess whether the impact of the proposed LB change is consistent with the principle that sufficient safety margins are maintained. Here also, the licensee is expected to choose the method of engineering analysis appropriate for evaluating whether sufficient safety margins would be maintained if the proposed LB change were implemented. An acceptable set of guidelines for making that assessment is summarized below. Other equivalent acceptance guidelines may also be used. 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.

Application-specific guidelines reflecting this general guidance have been developed and may be found in the application-specific regulatory guides (Refs. 5-8).

### 2.2.2 Evaluation of Risk Impact, Including Treatment of Uncertainties

The licensee's risk assessment may be used to address the principle that proposed increases in CDF and risk are small and are consistent with the intent of the NRC's Safety Goal Policy Statement (Ref. 4). For purposes of implementation, the licensee should assess the expected change in CDF and LERF. The necessary sophistication of the evaluation, including the scope of the PRA (e.g., internal events only, full power only), depends on the contribution the risk assessment makes to the integrated decisionmaking, which depends to some extent on the magnitude of the potential risk impact. For LB changes that may have a more substantial impact, an in-depth and comprehensive PRA analysis, one appropriate to derive a quantified estimate of the total impact of the proposed LB change, will be necessary to provide adequate justification. In other applications, calculated risk-importance measures or bounding estimates will be adequate. In still others, a qualitative assessment of the impact of the LB change on the plant's risk may be sufficient.

The remainder of this section discusses the use of quantitative PRA results in decisionmaking. This discussion has three parts:

**1.** A fundamental element of NRC's risk-informed regulatory process is a PRA of sufficient scope, level of detail, and technical acceptability for the intended application. Section 2.2.3 discusses the staff's expectations with respect to the needed PRA's scope, level of detail, and technical acceptability.

**2.** PRA results are to be used in this decisionmaking process in two ways—to assess the overall baseline CDF/LERF of the plant and to assess the CDF/LERF impact of the proposed change. Section 2.2.4 discusses the acceptance guidelines to be used by the staff for each of these measures.

**3.** One of the strengths of the PRA framework is its ability to characterize the impact of uncertainty in the analysis, and it is essential that these uncertainties be recognized when assessing whether the principles are being met. Section 2.2.5 provides guidelines on how the uncertainty is to be addressed in the decisionmaking process.

The staff's decision on the proposed LB change will be based on its independent judgment and review of the entire application.

### 2.2.3 Quality of PRA Analysis

The quality of a PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, and technical acceptability. The scope, level of detail, and technical acceptability of the PRA are to be commensurate with the application for which it is intended and the role the PRA results play in the integrated decision process. The more emphasis that is put on the risk insights and on PRA results in the decisionmaking process, the

more requirements that have to be placed on the PRA, in terms of both scope and how well the risk and the change in risk is assessed.

Conversely, emphasis on the PRA scope, level of detail, and technical acceptability can be reduced if a proposed change to the LB results in a risk decrease or is very small, or if the decision could be based mostly on traditional engineering arguments, or if compensating measures are proposed such that it can be convincingly argued that the change is very small.

Since this regulatory guide is intended for a variety of applications, the required scope, level of detail, and technical acceptability may vary. One over-riding requirement is that the PRA should realistically reflect the actual design, construction, operational practices, and operational experience of the plant and its owner. This should include the licensee's voluntary actions as well as regulatory requirements, and the PRA used to support risk-informed decisionmaking should also reflect the impact of previous changes made to the LB.

#### 2.2.3.1 Scope

Although the assessment of the risk implications in light of the acceptance guidelines discussed in Section 2.2.4 requires that all plant operating modes and initiating events be addressed, it is not necessary to have a PRA of such scope that it treats all operating modes and initiating events. A qualitative treatment of the missing modes and initiators may be sufficient in many cases. Section 2.2.5 discusses this further.

#### 2.2.3.2 Level of Detail Required To Support an Application

The level of detail required of the PRA is that which is sufficient to model the impact of the proposed change. The characterization of the problem should include establishing a cause-effect relationship to identify portions of the PRA affected by the issue being evaluated. Full-scale applications of the PRA should reflect this cause-effect relationship in a quantification of the impact on the PRA elements. For applications like component categorization, sensitivity studies on the effects of the change may be sufficient. For other applications it may be adequate to define the qualitative relationship of the impact on the PRA elements or only identify which elements are impacted.

If the impacts of a change to the plant cannot be associated with elements of the PRA, the PRA should be modified accordingly or the impact of the change should be evaluated qualitatively as part of the integrated decisionmaking process, as discussed in Section 2.2.6. In any case, the effects of the changes on the reliability and unavailability of systems, structures, and components or on operator actions should be appropriately accounted for.

#### 2.2.3.3 PRA Technical Acceptability

In the current context, technical acceptability will be understood as being determined by the adequacy of the actual modeling and the reasonableness of the assumptions and approximations. A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices, commensurate with the scope and level of detail required as discussed above. Several different approaches may be used to assess the technical acceptability of a PRA. One approach a licensee could use to assess technical acceptability is to perform a peer review of the PRA. The documentation should include the qualification of the

reviewers, the summarized review findings, and resolutions to these findings where applicable. Industry PRA certification programs and PRA cross-comparison studies could also be used to help assess appropriate scope, level of detail, and technical acceptability of the PRA. If such programs or studies are to be used, a description of the program, including the approach and standard or guidelines to which the PRA is compared, the depth of the review, and the make-up and qualifications of the personnel involved should be provided for NRC review. Based on the peer review or certification process and on the findings from this process, the licensee should justify why the PRA is adequate for the present application in terms of scope, level of detail, and technical acceptability. A staff review cannot be replaced in its entirety by a peer review, a certification, or cross-comparison; although the more confidence the staff has in the review that has been performed for the licensee, the less rigor should be expected in the staff review.

The NRC staff is currently developing a regulatory guide to endorse the American Society of Mechanical Engineers (ASME) PRA standard.[4] This new guide will provide guidance on how the PRA standard may be used to better understand the level of confidence in the PRA results and their role in decisionmaking. The guide will also endorse PRA standards or industry programs, including exceptions or additional staff requirements.

The NRC continues to support ongoing initiatives to develop industry PRA standards and expects to endorse PRA standards that are suitable for regulatory decisionmaking as described in this regulatory guide. Other standards for external events (e.g., seismic events) and low power and shutdown conditions are under development.[5] In the interim, the NRC staff is continuing to evaluate PRAs submitted in support of specific applications using the guidelines given in Section 2.2.3 and Section 2.5 of this regulatory guide, Chapter 19 of the Standard Review Plan (Ref. 3), and the information in SECY-00-0162 (Ref. 10), which defines minimum technical attributes for a technically acceptable PRA. In addition, the references and bibliography provide information that licensees may find useful in deciding on the acceptability of their PRA.

### 2.2.4 Acceptance Guidelines

The risk-acceptance guidelines presented in this regulatory guide are based on the principles and expectations for risk-informed regulation discussed in Section 2, and they are structured as follows. Regions are established in the two planes generated by a measure of the baseline risk metric (CDF or LERF) along the x-axis, and the change in those metrics ($\Delta$CDF or $\Delta$LERF) along the y-axis (Figures 3 and 4) and acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full-scope (including internal events, external events, full power, low power, and shutdown) assessment of the change in risk metric, and when necessary, as discussed below, the baseline value of the risk metric

[4] The American Society of Mechanical Engineers (ASME) recently issued "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," ASME RA-S-2002, which covers Level 1 and Level 2 (LERF only) PRAs for internal events (excluding fire) that occur during full-power operations.

[5] The American Nuclear Society (ANS) is developing a draft standard for external events (e.g., seismic events, including seismic margins, wind, flood), "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications: External Events." The ANS is also developing a draft standard for low-power and shutdown conditions, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications: Low Power and Shutdown." In addition, the various engineering professional societies are considering developing a fire PRA.

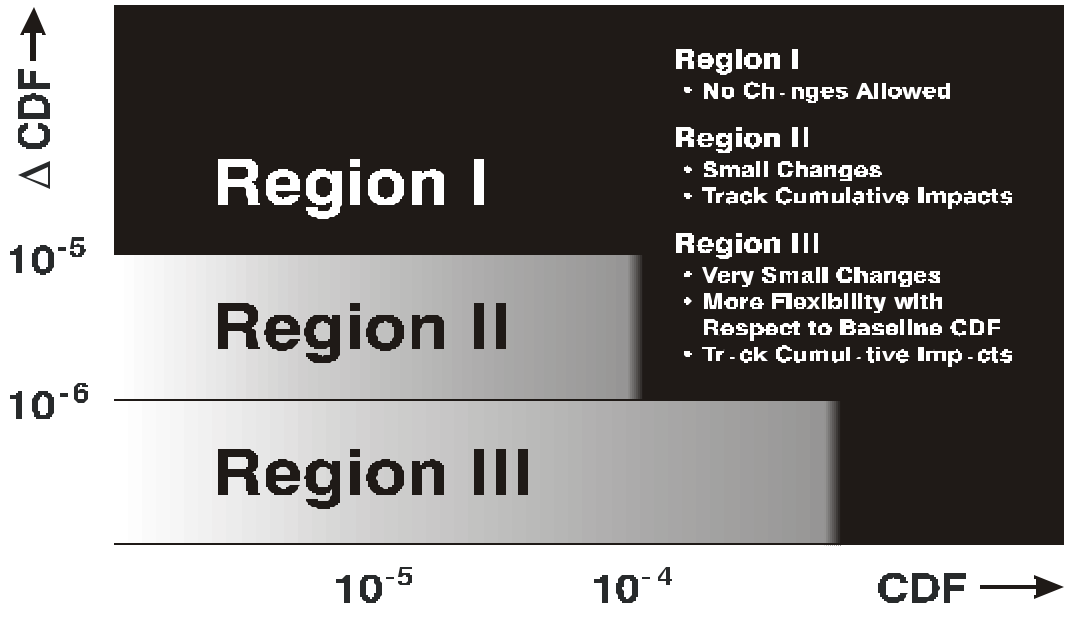


**Figure 3. Acceptance Guidelines* for Core Damage Frequency (CDF)**

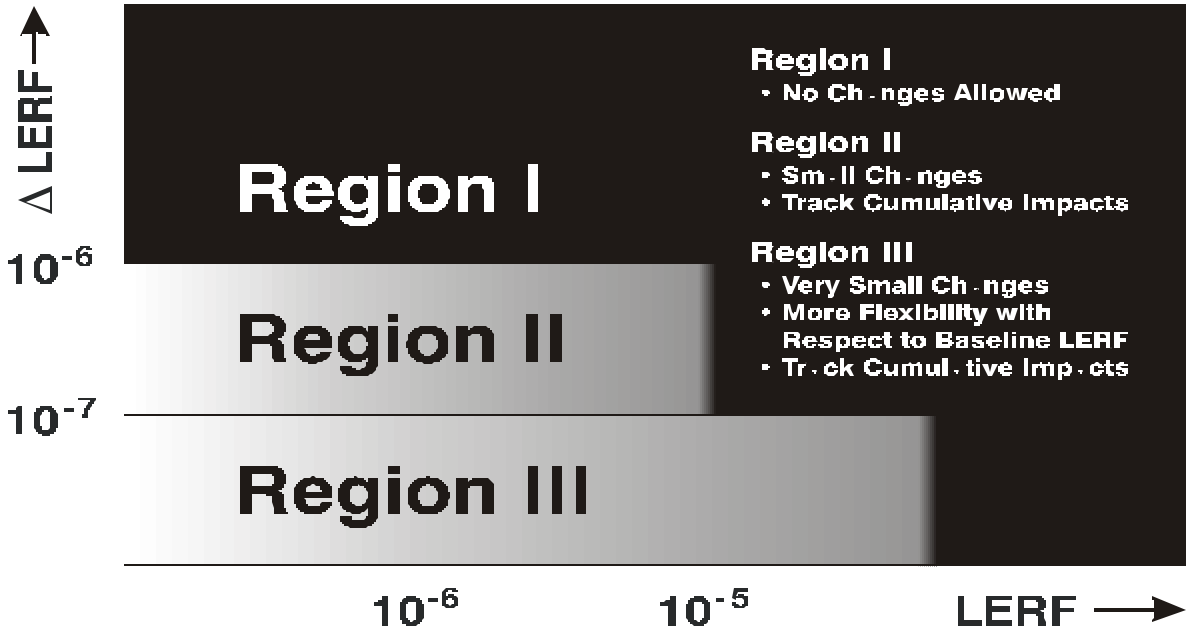


**Figure 4 Acceptance Guidelines* for Large Early Release Frequency (LERF)**

* The analysis will be subject to increased technical review and management attention as indicated by the darkness of the shading of the figure. In the context of the integrated decisionmaking, the boundaries between regions should not be interpreted as being definitive; the numerical values associated with defining the regions in the figure are to be interpreted as indicative values only.

(CDF or LERF). However, it is recognized that many PRAs are not full scope and PRA information of less than full scope may be acceptable as discussed in Section 2.2.5 of this regulatory guide.

There are two sets of acceptance guidelines, one for CDF and one for LERF, and ***both*** sets should be used.

- If the application clearly can be shown to result in a decrease in CDF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to CDF. (Because Figure 3 is drawn on a log scale, this region is not explicitly indicated on the figure.)

- When the calculated increase in CDF is very small, which is taken as being less than $10^{-6}$ per reactor year, the change will be considered regardless of whether there is a calculation of the total CDF (Region III). While there is no requirement to calculate the total CDF, if there is an indication that the CDF may be considerably higher than $10^{-4}$ per reactor year, the focus should be on finding ways to decrease rather than increase it. Such an indication would result, for example, if (1) the contribution to CDF calculated from a limited scope analysis, such as the individual plant examination (IPE) or the individual plant examination of external events (IPEEE), significantly exceeds $10^{-4}$, (2) a potential vulnerability has been identified from a margins-type analysis, or (3) historical experience at the plant in question has indicated a potential safety concern.

- When the calculated increase in CDF is in the range of $10^{-6}$ per reactor year to $10^{-5}$ per reactor year, applications will be considered only if it can be reasonably shown that the total CDF is less than $10^{-4}$ per reactor year (Region II).

- Applications that result in increases to CDF above $10^{-5}$ per reactor year (Region I) would not normally be considered.

**AND**

- If the application clearly can be shown to result in a decrease in LERF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to LERF. (Because Figure 4 is drawn with a log scale, this region is not explicitly indicated on the figure.)

- When the calculated increase in LERF is very small, which is taken as being less than $10^{-7}$ per reactor year, the change will be considered regardless of whether there is a calculation of the total LERF (Region III). While there is no requirement to calculate the total LERF, if there is an indication that the LERF may be considerably higher than $10^{-5}$ per reactor year, the focus should be on finding ways to decrease rather than increase it. Such an indication would result, for example, if (1) the contribution to LERF calculated from a limited scope analysis, such as the IPE or the IPEEE, significantly exceeds $10^{-5}$, (2) a potential vulnerability has been identified from a margins-type analysis, or (3) historical experience at the plant in question has indicated a potential safety concern.

- When the calculated increase in LERF is in the range of $10^{-7}$ per reactor year to $10^{-6}$ per reactor year, applications will be considered only if it can be reasonably shown that the total LERF is less than $10^{-5}$ per reactor year (Region II).

- Applications that result in increases to LERF above $10^{-6}$ per reactor year (Region I) would not normally be considered.

These guidelines are intended to provide assurance that proposed increases in CDF and LERF are small and are consistent with the intent of the Commission's Safety Goal Policy Statement (Ref. 4).

As indicated by the shading on the figures, the change request will be subject to an NRC technical and management review that will become more intensive when the calculated results are closer to the region boundaries.

The guidelines discussed above are applicable for full-power, low-power, and shutdown operations. However, during certain shutdown operations when the containment function is not maintained, the LERF guideline as defined above is not practical. In those cases, licensees may use more stringent baseline CDF guidelines (e.g., $10^{-5}$ per reactor year) to maintain an equivalent risk profile or may propose an alternative guideline to LERF that meets the intent of Principle 4 (see Figure 1).

Current LERF guidelines are based on assumptions of reactor power level, fuel burnup, and extent of the use of mixed oxide fuel. The staff is undertaking an evaluation of the impact, if any, of increases in these parameter on LERF.

The technical review that relates to the risk evaluation will address the scope, level of detail, and technical acceptability of the analysis, including consideration of uncertainties as discussed in the next section. Aspects covered by the management review are discussed in Section 2.2.6, Integrated Decisionmaking, and include factors that are not amenable to PRA evaluation.

### 2.2.5 Comparison of PRA Results with the Acceptance Guidelines

This section provides guidance on comparing the results of the PRA with the acceptance guidelines described in Section 2.2.4. In the context of integrated decisionmaking, the acceptance guidelines should not be interpreted as being overly prescriptive. They are intended to provide an indication, in numerical terms, of what is considered acceptable. As such, the numerical values associated with defining the regions in Figures 3 and 4 of this regulatory guide are approximate values that provide an indication of the changes that are generally acceptable. Furthermore, the state-of-knowledge, or epistemic, uncertainties associated with PRA calculations preclude a definitive decision with respect to which region the application belongs in based purely on the numerical results.

The intent of comparing the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4, discussed in Section 2, is being met. This decision

must be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not. This is a somewhat subjective process, and the reasoning behind the decisions must be well documented. Guidance on what should be addressed follows in Section 2.2.5.4; but first, the types of uncertainty that impact PRA results and methods typically used for their analysis are briefly discussed. More information can be found in some of the publications in the Bibliography.

#### 2.2.5.1 Types of Uncertainty and Methods of Analysis

There are two facets to uncertainty that, because of their natures, must be treated differently when creating models of complex systems. They have recently been termed aleatory and epistemic uncertainty. The aleatory uncertainty is that addressed when the events or phenomena being modeled are characterized as occurring in a "random" or "stochastic" manner, and probabilistic models are adopted to describe their occurrences. It is this aspect of uncertainty that gives PRA the probabilistic part of its name. The epistemic uncertainty is that associated with the analyst's confidence in the predictions of the PRA model itself, and it reflects the analyst's assessment of how well the PRA model represents the actual system being modeled. This has been referred to as state-of-knowledge uncertainty. In this section, it is the epistemic uncertainty that is discussed; the aleatory uncertainty is built into the structure of the PRA model itself.

Because they are generally characterized and treated differently, it is useful to identify three classes of uncertainty that are addressed in and impact the results of PRAs: parameter uncertainty, model uncertainty, and completeness uncertainty. Completeness uncertainty can be regarded as one aspect of model uncertainty, but because of its importance, it is discussed separately. The Bibliography may be consulted for additional information on definitions of terms and approaches to the treatment of uncertainty in PRAs.

#### 2.2.5.2 Parameter Uncertainty

Each of the models that is used, either to develop the PRA logic structure or to represent the basic events of that structure, has one or more parameters. Typically, each of these models (e.g., the Poisson model for initiating events) is assumed to be appropriate. However, the parameter values for these models are often not known perfectly. Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. They are typically characterized by establishing probability distributions on the parameter values. These distributions can be interpreted as expressing the analyst's degree of belief in the values these parameters could take, based on his state of knowledge and conditional on the underlying model being correct. It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results (e.g., CDF, accident sequence frequencies, LERF) of the PRA. However, the analysis must be done to correlate the sample values for different PRA elements from a group to which the same parameter value applies (the so-called state-of-knowledge dependency; see Ref. 11).

#### 2.2.5.3 Model Uncertainty

The development of the PRA model is supported by the use of models for specific events or phenomena. In many cases, the industry's state of knowledge is incomplete, and there may be

different opinions on how the models should be formulated. Examples include approaches to modeling human performance, common cause failures, and reactor coolant pump seal behavior upon loss of seal cooling. This gives rise to model uncertainty. In many cases, the appropriateness of the models adopted is not questioned and these models have become, de facto, the standard models to use.

Examples include the use of Poisson and binomial models to characterize the probability of occurrence of component failures. For some issues with well-formulated alternative models, PRAs have addressed model uncertainty by using discrete distributions over the alternative models, with the probability associated with a specific model representing the analyst's degree of belief that that model is the most appropriate. A good example is the characterization of the seismic hazard as different hypotheses lead to different hazard curves, which can be used to develop a discrete probability distribution of the initiating event frequency for earthquakes. Other examples can be found in the Level 2 analysis.

Another approach to addressing model uncertainty has been to adjust the results of a single model through the use of an adjustment factor. However it is formulated, an explicit representation of model uncertainty can be propagated through the analysis in the same way as parameter uncertainty. More typically, however, particularly in the Level 1 analysis, the use of different models would result in the need for a different structure (e.g., with different thermal hydraulic models used to determine success criteria). In such cases, uncertainties in the choice of an appropriate model are typically addressed by making assumptions and, as in the case of the component failure models discussed above, adopting a specific model.

PRAs model the continuum of possible plant states in a discrete way, and are, by their very nature, approximate models of the world. This results in some random (aleatory) aspects of the 'world' not being addressed except in a bounding way, e.g., different realizations of an accident sequence corresponding to different LOCA sizes (within a category) are treated by assuming a bounding LOCA, with the time of failure of an operating component assumed to occur at the moment of demand. These approximations introduce biases (uncertainties) into the results.

In interpreting the results of a PRA, it is important to develop an understanding of the impact of a specific assumption or choice of model on the predictions of the PRA. This is true even when the model uncertainty is treated probabilistically, since the probabilities, or weights, given to different models would be subjective. The impact of using alternative assumptions or models may be addressed by performing appropriate sensitivity studies, or they may be addressed using qualitative arguments, based on an understanding of the contributors to the results and how they are impacted by the change in assumptions or models. The impact of making specific modeling approximations may be explored in a similar manner.

#### 2.2.5.4 Completeness Uncertainty

Completeness is not in itself an uncertainty, but a reflection of scope limitations. The result is, however, an uncertainty about where the true risk lies. The problem with completeness uncertainty is that, because it reflects an unanalyzed contribution, it is difficult (if not impossible) to estimate its magnitude. Some contributions are unanalyzed not because methods are not available, but because they have not been refined to the level of the analysis of internal events.

Examples are the analysis of some external events and the low-power and shutdown modes of operation. There are issues, however, for which methods of analysis have not been developed, and they have to be accepted as potential limitations of the technology. Thus, for example, the impact on actual plant risk from unanalyzed issues such as the influences of organizational performance cannot now be explicitly assessed.

The issue of completeness of scope of a PRA can be addressed for those scope items for which methods are in principle available, and therefore some understanding of the contribution to risk exists, by supplementing the analysis with additional analysis to enlarge the scope, using more restrictive acceptance guidelines, or by providing arguments that, for the application of concern, the out-of-scope contributors are not significant. Approaches acceptable to the NRC staff for dealing with incompleteness are discussed in the next section.

#### 2.2.5.5 Comparisons with Acceptance Guidelines

The different regions of the acceptance guidelines require different depths of analysis. Changes resulting in a net decrease in the CDF and LERF estimates do not require an assessment of the calculated baseline CDF and LERF. Generally, it should be possible to argue on the basis of an understanding of the contributors and the changes that are being made that the overall impact is indeed a decrease, without the need for a detailed quantitative analysis.

If the calculated values of CDF and LERF are very small, as defined by Region III in Figures 3 and 4, a detailed quantitative assessment of the baseline value of CDF and LERF will not be necessary. However, if there is an indication that the CDF or LERF could considerably exceed $10^{-4}$ and $10^{-5}$ respectively, in order for the change to be considered the licensee may be required to present arguments as to why steps should not be taken to reduce CDF or LERF. Such an indication would result, for example, if (1) the contribution to CDF or LERF calculated from a limited scope analysis, such as the IPE or the IPEEE, significantly exceeds $10^{-4}$ and $10^{-5}$ respectively, (2) there has been an identification of a potential vulnerability from a margins-type analysis, or (3) historical experience at the plant in question has indicated a potential safety concern.

For larger values of $\Delta$CDF and $\Delta$LERF, which lie in the range used to define Region II, an assessment of the baseline CDF and LERF is required.

To demonstrate compliance with the numerical guidelines, the level of detail required in the assessment of the values and the analysis of uncertainty related to model and incompleteness issues will depend on both (1) the LB change being considered and (2) the importance of the demonstration that Principle 4 has been met. In Region III of Figures 3 and 4, the closer the estimates of $\Delta$CDF or $\Delta$LERF are to their corresponding acceptance guidelines, the more detail will be required. Similarly, in Region II of Figures 3 and 4, the closer the estimates of $\Delta$CDF or $\Delta$LERF and CDF and LERF are to their corresponding acceptance guidelines, the more detail will be required. In a contrasting example, if the estimated value of a particular metric is very small compared to the acceptance goal, a simple bounding analysis may suffice with no need for a detailed uncertainty analysis.

Because of the way the acceptance guidelines were developed, the appropriate numerical measures to use in the initial comparison of the PRA results to the acceptance guidelines are mean

values. The mean values referred to are the means of the probability distributions that result from the propagation of the uncertainties on the input parameters and those model uncertainties explicitly represented in the model. While a formal propagation of the uncertainty is the best way to correctly account for state-of-knowledge uncertainties that arise from the use of the same parameter values for several basic event probability models, under certain circumstances, a formal propagation of uncertainty may not be required if it can be demonstrated that the state-of-knowledge correlation is unimportant. This will involve, for example, a demonstration that the bulk of the contributing scenarios (cutsets or accident sequences) do not involve multiple events that rely on the same parameter for their quantification.

Consistent with the viewpoint that the guidelines are not to be used prescriptively, even if the calculated ÎCDF and ÎLERF values are such that they place the change in Region I or II, it may be possible to make a case that the application should be treated as if it were in Region II or III if, for example, it is shown that there are unquantified benefits that are not reflected in the quantitative risk results. However, care should be taken that there are no unquantified detrimental impacts of the change, such as an increase in operator burden. In addition, if compensatory measures are proposed to counter the impact of the major risk contributors, even though the impact of these measures may not be estimated numerically, such arguments will be considered in the decision process.

While the analysis of parametric uncertainty is fairly mature, and is addressed adequately through the use of mean values, the analysis of the model and completeness uncertainties cannot be handled in such a formal manner. Whether the PRA is full scope or only partial scope, and whether it is only the change in metrics or both the change and baseline values that need to be estimated, it will be incumbent on the licensee to demonstrate that the choice of reasonable alternative hypotheses, adjustment factors, or modeling approximations or methods to those adopted in the PRA model would not significantly change the assessment. This demonstration can take the form of well formulated sensitivity studies or qualitative arguments. In this context, "reasonable" is interpreted as implying some precedent for the alternative, such as use by other analysts, and also that there is a physically reasonable basis for the alternative. It is not the intent that the search for alternatives should be exhaustive and arbitrary. For the decisions that involve only assessing the change in metrics, the number of model uncertainty issues to be addressed will be smaller than for the case of the baseline values, when only a portion of the model is affected. The alternatives that would drive the result toward unacceptableness should be identified and sensitivity studies performed or reasons given as to why they are not appropriate for the current application or for the particular plant. In general, the results of the sensitivity studies should confirm that the guidelines are still met even under the alternative assumptions (i.e., change generally remains in the appropriate region). Alternatively, this analysis can be used to identify candidates for compensatory actions or increased monitoring. The licensee should pay particular attention to those assumptions that impact the parts of the model being exercised by the change.

When the PRA is not full scope, it is necessary for the licensee to address the significance of the out-of-scope items. The importance of assessing the contribution of the out-of-scope portions of the PRA to the base case estimates of CDF and LERF is related to the margin between the as-calculated values and the acceptance guidelines. When the contributions from the modeled contributors are close to the guidelines, the argument that the contribution from the missing items

is not significant must be convincing, and in some cases may require additional PRA analyses. When the margin is significant, a qualitative argument may be sufficient. The contribution of the out-of-scope portions of the model to the change in metric may be addressed by bounding analyses, detailed analyses, or by a demonstration that the change has no impact on the unmodeled contributors to risk. In addition, it should be demonstrated that changes based on a partial PRA do not disproportionately change the risk associated with those accident sequences that arise from the modes of operation not included in the PRA.

One alternative to an analysis of uncertainty is to design the proposed LB change such that the major sources of uncertainty will not have an impact on the decisionmaking process. For example, in the region of the acceptance guidelines where small increases are allowed regardless of the value of the baseline CDF or LERF, the proposed change to the LB could be designed such that the modes of operation or the initiating events that are missing from the analysis would not be affected by the change. In these cases, incompleteness would not be an issue. Similarly, in such cases, it would not be necessary to address all the model uncertainties, but only those that impact the evaluation of the change.

If only a Level 1 PRA is available, in general, only the CDF is calculated and not the LERF. An approach is presented in Reference 9 that allows a subset of the core damage accidents identified in the Level 1 analysis to be allocated to a release category that is equivalent to a LERF. The approach uses simplified event trees that can be quantified by the licensee on the basis of the plant configuration applicable to each accident sequence in the Level 1 analysis. The frequency derived from these event trees can be compared to the LERF acceptance guidelines. The approach described in Reference 9 may be used to estimate LERF only in those cases when the plant is not close to the CDF and LERF benchmark values.

### 2.2.6 Integrated Decisionmaking

In making a regulatory decision, risk insights are integrated with considerations of defense in depth and safety margins. The degree to which the risk insights play a role, and therefore the need for detailed staff review, is application dependent.

Quantitative risk results from PRA calculations are typically the most useful and complete characterization of risk, but they are generally supplemented by qualitative risk insights and traditional engineering analysis. Qualitative risk insights include generic results that have been learned from the numerous PRAs that have been performed in the past decades and from operational experience. For example, if one is deciding which motor-operated valves in a plant can be subject to less frequent testing, the plant-specific PRA results can be compared with results from similar plants. This type of comparison can give support to the licensee's analysis and reduce the reliance of the staff review on the technical acceptability of the licensee PRA. However, as a general rule, applications that impact large numbers of SSCs will benefit from a PRA of high quality.

Traditional engineering analysis provides insight into available margins and defense in depth. In the example of the operational assessment of steam generator tubes discussed later in this section, it is traditional engineering analysis that provides assurance that structural integrity and

leakage criteria have been satisfied. With few exceptions, these assessments are performed without any quantification of risk.

The results of the different elements of the engineering analyses discussed in Sections 2.2.1 and 2.2.2 must be considered in an integrated manner. None of the individual analyses is sufficient in and of itself. In this way, it can be seen that the decision will not be driven solely by the numerical results of the PRA. They are one input into the decisionmaking and help in building an overall picture of the implications of the proposed change on risk. The PRA has an important role in putting the change into its proper context as it impacts the plant as a whole. The PRA analysis is used to demonstrate that Principle 4 has been satisfied. As the discussion in the previous section indicates, both quantitative and qualitative arguments may be brought to bear. Even though the different pieces of evidence used to argue that the principle is satisfied may not be combined in a formal way, they need to be clearly documented.

In general, a risk-informed application will require some quantitative risk calculations using PRA methods. In some cases, the use of PRA will be extensive and will be crucial to the success of the application. There are some proposals for real-time use of the PRA and associated risk management software as a tool to assess plant configuration. The more ambitious proposals involve the use of "risk meters." For example, the NRC and industry are cooperating on the risk-informed standard technical specification (RI-STS) project. If such a process were eventually adopted, one element might be to replace the traditional limiting conditions for operation (LCO) action statements with a PRA-oriented approach. When a licensee encounters an LCO, rather than shutting down the plant, it might be authorized to use the plant PRA to determine an appropriate configuration that represents an acceptable level of risk. Such a broad scope application would require a detailed PRA model that is capable of evaluating the risk associated with specific plant configurations. Since the configuration-specific risk could be affected by any of the elements of the model, this requires that the model be of relatively high quality.

There are, however, some applications that, because of the nature of the proposed change, have a limited impact on risk, and this is reflected in the impact on the elements of the risk model.

An example is risk-informed inservice inspection (RI-ISI). In this application, risk significance was used as one criterion for selecting pipe segments to be periodically examined for cracking. During the staff review it became clear that a high level of emphasis on PRA technical acceptability was not necessary. Therefore, the staff review of plant-specific RI-ISI typically will include only a limited scope review of PRA technical acceptability.

The scope of implementation of the risk-informed decision will be a function of the confidence the NRC staff has in the results of the analysis. As indicated, one important factor that can be considered when determining the degree of implementation of the change is the ability to monitor the performance to limit the potential risk. In many applications, the potential risk can be limited by defining specific measures and criteria that must be monitored subsequent to approval. When relying on performance monitoring, the staff must have assurance that the measures truly represent the potential for risk increase and that the criteria are set at reasonable limits. Moreover, one must be sure that degrading performance can be detected in a timely fashion, long before a

significant public health issue results. The impact of the monitoring can be fed back into the analysis to demonstrate how it supports the decision.

An example of this is the management of steam generator tube degradation. The NRC staff is working with industry to approve licensee use of NEI-97-06 (Ref. 12), a guidance document for determining what tubes can be left in service and how frequently steam generators need to be inspected. The guidance in NEI-97-06 includes guidance for licensees to perform an operational assessment prior to restart from an outage. Any tubes that exceed certain limits must be repaired or removed from service. The licensee must determine whether the tubes left in service will meet structural strength and leakage criteria at the end of the cycle. If not, the licensee must take compensatory action, such as a mid-cycle inspection. At the end of the cycle, the licensee must perform condition monitoring, in which the actual condition is examined to determine whether the actual performance met the criteria. Any unfavorable deviation of the actual tube behavior from the predicted performance must be accounted for in subsequent operational assessment. In this example, performance monitoring (condition monitoring) is relied upon to assure that any deviations from acceptance criteria are detected promptly. Moreover, the results are used to improve the analysis techniques to limit potential deviations in future cycles.

The NRC review of an application will take all these factors into consideration. The review of PRA technical acceptability in particular will focus on those aspects that impact the results used in the decision and on the degree of confidence required in those results. A limited application would lead the staff to conduct a more limited review of the risk estimates, and therefore to place less emphasis on the technical acceptability of the PRA than would be the case for a broad-scope application.

Finally, when implementing a decision, the licensee may choose to compensate for lack of confidence in the analysis by restricting the degree of implementation. This has been the technique used in several applications involving SSC categorization into low or high safety significance. In general, unless there is compelling evidence that the SSC is of low safety significance, it is maintained as high safety significant. This requires a reasonable understanding of the limitations of the PRA. Another example of risk limitation is the placing of restrictions on the application. For example, risk-informed technical-specification-allowed outage time changes are accompanied by implementation of a configuration risk management program, which requires licensees to examine their plant configuration before voluntarily entering the approved condition.

In Section 2.2.4, it was indicated that the application would be given increased NRC management attention when the calculated values of the changes in the risk metrics, and their baseline values when appropriate, approached the guidelines. Therefore, the issues in the submittal expected to be addressed include:

- The cumulative impact of previous changes and the trend in CDF (the licensee's risk management approach);

- The cumulative impact of previous changes and the trend in LERF (the licensee's risk management approach);

- The impact of the proposed change on operational complexity, burden on the operating staff, and overall safety practices;

- Plant-specific performance and other factors (for example, siting factors, inspection findings, performance indicators, and operational events), and Level 3 PRA information, if available;

- The benefit of the change in relation to its CDF/LERF increase;

- The practicality of accomplishing the change with a smaller CDF/LERF impact; and

- The practicality of reducing CDF/LERF when there is reason to believe that the baseline CDF/LERF are above the guideline values (i.e., $10^{-4}$ and $10^{-5}$ per reactor year).

## 2.3 ELEMENT 3: DEFINE IMPLEMENTATION AND MONITORING PROGRAM

Careful consideration should be given to implementation and performance-monitoring strategies. The primary goal for this element is to ensure that no adverse safety degradation occurs because of the changes to the LB. The staff's principal concern is the 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. Therefore, an implementation and monitoring plan should be developed to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of SSCs that have been evaluated. This will ensure that the conclusions that have been drawn from the evaluation remain valid. Further details of acceptable processes for implementation in specific applications are discussed in application-specific regulatory guides (Refs. 5-8).

Decisions concerning the implementation of changes should be made in light of the uncertainty associated with the results of the traditional and probabilistic engineering evaluations. Broad implementation within a limited time period may be justified when uncertainty is shown to be low (data and models are adequate, engineering evaluations are verified and validated, etc.), whereas a slower, phased approach to implementation (or other modes of partial implementation) would be expected when uncertainty in evaluation findings is higher and where programmatic changes are being made that could impact SSCs across a wide spectrum of the plant, such as in inservice testing, inservice inspection, and graded quality assurance (IST, ISI, and graded QA). In such situations, the potential introduction of common cause effects must be fully considered and included in the submittal.

The staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that support the change to the LB. The program should be capable of trending equipment performance after a change has been implemented to demonstrate that performance is consistent with that assumed in the traditional engineering and probabilistic analyses that were conducted to justify the change. This may include monitoring associated with non-safety-related SSCs if the analysis determines those SSCs to be

risk significant. The program should be structured such that (1) SSCs are monitored commensurate with their safety importance, i.e., monitoring for SSCs categorized as having low safety significance may be less rigorous than that for SSCs of high safety significance, (2) feedback of information and corrective actions is accomplished in a timely manner, and (3) degradation in SSC performance is detected and corrected before plant safety can be compromised. The potential impact of observed SSC degradation on similar components in different systems throughout the plant should be considered.

The staff expects that licensees will integrate, or at least coordinate, their monitoring for risk-informed changes with existing programs for monitoring equipment performance and other operating experience on their site and throughout the industry. In particular, monitoring that is performed in conformance with the Maintenance Rule (10 CFR 50.65) can be used when the monitoring performed under the Maintenance Rule is sufficient for the SSCs affected by the risk-informed application. If an application requires monitoring of SSCs that are not included in the Maintenance Rule, or has a greater resolution of monitoring than the Maintenance Rule (component vs. train or plant-level monitoring), it may be advantageous for a licensee to adjust the Maintenance Rule monitoring program rather than to develop additional monitoring programs for risk-informed purposes. In these cases, the performance criteria chosen should be shown to be appropriate for the application in question. It should be noted that plant or licensee performance under actual design conditions may not be readily measurable. When actual conditions cannot be monitored or measured, whatever information most closely approximates actual performance data should be used. For example, establishing a monitoring program with a performance-based feedback approach may combine some of the following activities:

- Monitoring performance characteristics under actual design basis conditions (e.g., reviewing actual demands on emergency diesel generators, reviewing operating experience)

- Monitoring performance characteristics under test conditions that are similar to those expected during a design basis event

- Monitoring and trending performance characteristics to verify aspects of the underlying analyses, research, or bases for a requirement (e.g., measuring battery voltage and specific gravity, inservice inspection of piping)

- Evaluating licensee performance during training scenarios (e.g., emergency planning exercises, operator licensing examinations)

- Component quality controls, including developing pre- and post-component installation evaluations (e.g., environmental qualification inspections, reactor protection system channel checks, continuity testing of boiling water reactor squib valves).

As part of the monitoring program, it is important that provisions for specific cause determination, trending of degradation and failures, and corrective actions be included. Such provisions should be applied to SSCs commensurate with their importance to safety as determined by the engineering evaluation that supports the LB change. A determination of cause is needed when performance expectations are not being met or when there is a functional failure of an

application-specific SSC that poses a significant condition adverse to performance. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or ensure that it is anticipated prior to becoming a safety concern. It should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications (as defined in Ref. 13).

Finally, in accordance with Criterion XVI of Appendix B to 10 CFR Part 50, the monitoring program should identify any corrective actions to preclude the recurrence of unacceptable failures or degraded performance. The circumstances surrounding the failure may indicate that the SSC failed because of adverse or harsh operating conditions (e.g., operating a valve dry, over-pressurization of a system) or failure of another component that caused the SSC failure. Therefore, corrective actions should also consider SSCs with similar characteristics with regard to operating, design, or maintenance conditions. The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

## 2.4 ELEMENT 4: SUBMIT PROPOSED CHANGE

Requests for proposed changes to the plant's LB typically take the form of requests for license amendments (including changes to or removal of license conditions), technical specification changes, changes to or withdrawals of orders, and changes to programs pursuant to 10 CFR 50.54 (e.g., QA program changes under 10 CFR 50.54(a)). Licensees should (1) carefully review the proposed LB change in order to determine the appropriate form of the change request, (2) ensure that information required by the relevant regulations in support of the request is developed, and (3) prepare and submit the request in accordance with relevant procedural requirements. For example, license amendments should meet the requirements of 10 CFR 50.90, 50.91, and 50.92, as well as the procedural requirements in 10 CFR 50.4. Risk information that the licensee submits in support of the LB change request should meet the guidance in Section 3 of this regulatory guide.

Licensees are free to decide whether to submit risk information in support of their LB change request. If the licensee's proposed change to the LB is consistent with currently approved staff positions, the staff's determination generally will be based solely on traditional engineering analyses without recourse to risk information (although the staff may consider any risk information submitted by the licensee). If the licensee's proposed change goes beyond currently approved staff positions, the staff normally will consider both information based on traditional engineering analyses and information based on risk insights. If the licensee does not submit risk information in support of an LB change that goes beyond currently approved staff positions, the staff may request the licensee to submit such information. If the licensee chooses not to provide the risk information, the staff will review the proposed application using traditional engineering analyses and determine whether sufficient information has been provided to support the requested change. However, if new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as the identification of an issue related to the requested LB change that may substantially increase risk (see Ref. 3), the NRC staff will request the licensee to submit risk-related information. The NRC staff will not approve the requested LB change until it has

reasonable assurance that the public health and safety will be adequately protected if the requested LB change is approved.

In developing the risk information set forth in this regulatory guide, licensees will likely identify SSCs with high risk significance that are not currently subject to regulatory requirements or are subject to a level of regulation that is not commensurate with their risk significance. It is expected that licensees will propose LB changes that will subject these SSCs to an appropriate level of regulatory oversight, consistent with the risk significance of each SSC. Specific information on the staff's expectations in this regard is set forth in the application-specific regulatory guides (Refs. 5-8).

## 2.5 QUALITY ASSURANCE

As stated in Section 2.2, the staff expects that the quality of the engineering analyses conducted to justify proposed LB changes will be appropriate for the nature of the change. In this regard, it is expected that for traditional engineering analyses (e.g., deterministic engineering calculations) existing provisions for quality assurance (e.g., Appendix B to 10 CFR Part 50, for safety-related SSCs) will apply and provide the appropriate quality needed. Likewise, when a risk assessment of the plant is used to provide insights into the decisionmaking process, the staff expects that the PRA will have been subject to quality control.

To the extent that a licensee elects to use PRA information to enhance or modify activities affecting the safety-related functions of SSCs, the following, in conjunction with the other guidance contained in this guide, describes methods acceptable to the NRC staff to ensure that the pertinent quality assurance requirements of Appendix B to 10 CFR Part 50 are met and that the PRA is sufficient to be used for regulatory decisions.

- Use personnel qualified for the analysis.

- Use procedures that ensure control of documentation, including revisions, and provide for independent review, verification, or checking of calculations and information used in the analyses (an independent peer review or certification program can be used as an important element in this process).

- Provide documentation and maintain records in accordance with the guidelines in Section 3 of this guide.

- Use procedures that ensure appropriate attention and corrective actions are taken if assumptions, analyses, or information used in previous decisionmaking are changed (e.g., licensee voluntary action) or determined to be in error.

When performance monitoring programs are used in the implementation of proposed changes to the LB, it is expected that those programs will be implemented by using quality assurance provisions commensurate with the safety significance of affected SSCs. An existing PRA or analysis can be utilized to support a proposed LB change, provided it can be shown that the appropriate quality provisions have been met.

# 3. DOCUMENTATION

## 3.1 Introduction

To facilitate the NRC staff's review to ensure that the analyses conducted were sufficient to conclude that the key principles of risk-informed regulation have been met, documentation of the evaluation process and findings are expected to be maintained. Additionally, the information submitted should include a description of the process used by the licensee to ensure its adequacy and some specific information to support the staff's conclusion regarding the acceptability of the requested LB change.

## 3.2 Archival Documentation

Archival documentation should include a detailed description of engineering analyses conducted and the results obtained, irrespective of whether they were quantitative or qualitative, or whether the analyses made use of traditional engineering methods or probabilistic approaches. This documentation should be maintained by the licensee, as part of the normal quality assurance program, so that it is available for examination. Documentation of the analyses conducted to support changes to a plant's LB should be maintained as lifetime quality records in accordance with Regulatory Guide 1.33 (Ref. 14).

## 3.3 Licensee Submittal Documentation

To support the NRC staff's conclusion that the proposed LB change is consistent with the key principles of risk-informed regulation and NRC staff expectations, the staff expects the following information will be submitted to the NRC:

- A description of how the proposed change will impact the LB (relevant principle: LB changes meet regulations).

- A description of the components and systems affected by the change, the types of changes proposed, the reason for the changes, and results and insights from an analysis of available data on equipment performance (relevant staff expectation: all safety impacts of the proposed LB change must be evaluated).

- A reevaluation of the LB accident analysis and the provisions of 10 CFR Parts 20 and 100, if appropriate (relevant principles: LB changes meet the regulations, sufficient safety margins are maintained, defense-in-depth philosophy).

- An evaluation of the impact of the LB change on the breadth or depth of defense-in-depth attributes of the plant (relevant principle: defense-in-depth philosophy).

- Identification of how and where the proposed change will be documented as part of the plant's LB (e.g., FSAR, technical specifications, licensing conditions). This should include proposed changes or enhancements to the regulatory controls for high-risk-significant SSCs

that are not subject to any requirements or the requirements are not commensurate with the SSC's risk significance.

The licensee should also identify:

- Key assumptions in the PRA that impact the application (e.g., voluntary licensee actions), elements of the monitoring program, and commitments made to support the application.

- SSCs for which requirements should be increased.

- The information to be provided as part of the plant's LB (e.g., FSAR, technical specifications, licensing condition).

- Whether provisions of Appendix B to 10 CFR Part 50 apply to the PRA. This comes into play if the PRA forms part of the basis used to enhance or modify safety-related functions of SSCs subject to those provisions. Thus, the licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis and in accordance with all applicable regulations and its QA program description.

An independent peer review can be an important element of ensuring technical acceptability. The licensee's submittal should discuss measures used to ensure it, such as a report of a peer review (when performed) that addresses the appropriateness of the PRA model for supporting a risk assessment of the LB change under consideration. The report should address any analysis limitations that are expected to impact the conclusion regarding acceptability of the proposed change.

The licensee's resolution of the findings of the peer review, certification, or cross comparison, when performed, should also be submitted. For example, this response could indicate whether the PRA was modified or could justify why no change was necessary to support decisionmaking for the LB change under consideration. As discussed in Section 2.2.2, the staff's decision on the proposed license amendment will be based on its independent judgment and review, as appropriate, of the entire application.

### 3.3.1 Risk Assessment Methods

In order to have confidence that the risk assessment conducted is adequate to support the proposed change, a summary of the risk assessment methods used should be submitted. Consistent with current practice, information submitted to the NRC for its consideration in making risk-informed regulatory decisions will be made publicly available, unless such information is deemed proprietary and justified as such. The following information should be submitted and is intended to illustrate that the scope, level of detail, and technical acceptability of the engineering analyses conducted to justify the proposed LB change are appropriate to the nature and scope of the change:

- A description of risk assessment methods used,

- The key modeling assumptions that are necessary to support the analysis or that impact the application,

- The event trees and fault trees necessary to support the analysis of the LB change, and

- A list of operator actions modeled in the PRA that impact the application and their error probabilities.

The submitted information that summarizes the results of the risk assessment should include:

- The effects of the change on the dominant sequences (sequences that contribute more than 5% to the risk) in order to show that the LB change does not create risk outliers and does not exacerbate existing risk outliers.

- An assessment of the change to CDF and LERF, including a description of the significant contributors to the change.

- Information related to assessment of the total plant CDF—the extent of the information required will depend on whether the analysis of the change in CDF is in Region II or Region III of Figure 3. The information could include quantitative (e.g., IPE or PRA results for internal initiating events, external event PRA results if available) and qualitative or semi-quantitative information (results of margins analyses, outage configuration studies).

- Information related to assessment of total plant LERF—the extent of the information required will depend on whether the analysis of the change in LERF is in Region II or Region III of Figure 4. The information could include quantitative (e.g., IPE or PRA results for internal initiating events, external event PRA results if available) and qualitative or semi-quantitative information (results of margins analyses, outage configuration studies).

- Results of analyses that show that the conclusions regarding the impact of the LB change on plant risk will not vary significantly under a different set of plausible assumptions.

- A description of the licensee process to ensure PRA technical acceptability and a discussion as to why the PRA is of sufficient quality to support the current application.

### 3.3.2 Cumulative Risks

As part of evaluation of risk, licensees should understand the effects of the present application in light of past applications. Optimally, the PRA used for the current application should already model the effects of past applications. However, qualitative effects and synergistic effects are sometimes difficult to model. Tracking changes in risk (both quantifiable and nonquantifiable) that are due to plant changes would provide a mechanism to account for the cumulative and synergistic effects of these plant changes and would help to demonstrate that the proposing licensee has a risk management philosophy in which PRA is not just used to systematically increase risk, but is also used to help reduce risk where appropriate and where it is

shown to be cost effective. The tracking of cumulative risk will also help the NRC staff in monitoring trends.

Therefore, as part of the submittal, the licensee should track and submit the impact of all plant changes that have been submitted for NRC review and approval. Documentation should include:

- The calculated change in risk for each application (CDF and LERF) and the plant elements (e.g., SSCs, procedures) affected by each change,
- Qualitative arguments that were used to justify the change (if any) and the plant elements affected by these arguments;
- Compensatory measures or other commitments used to help justify the change (if any) and the plant elements affected, and
- Summarized results from the monitoring programs (where applicable) and a discussion of how these results have been factored into the PRA or into the current application.

As an option, the submittal could also list (but not submit to the NRC) past changes to the plant that reduced the plant risk, especially those changes that are related to the current application. A discussion of whether these changes are already included in the base PRA model should also be included.

## 3.4 IMPLEMENTATION PLAN AND PERFORMANCE MONITORING DOCUMENTATION

As described in Section 2.3, a key principle of risk-informed regulation is that proposed performance implementation and monitoring strategies reflect uncertainties in analysis models and data. Consequently, the submittal should include a description and rationale for the implementation and performance monitoring strategy for the proposed LB change.

## REFERENCES


1. USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," *Federal Register,* Vol. 60, p. 42622 (60 FR 42622), August 16, 1995.

2. USNRC, “Risk-Informed Regulation Implementation Plan,” SECY-00-0213, October 16, 2000; updated December 5, 2001 as SECY-01-0218.[1]

3. USNRC, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," Revision 1 of Chapter 19 of the Standard Review Plan, NUREG-0800, June 2002.[2]

4. USNRC, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," *Federal Register*, Vol. 51, p. 30028 (51 FR 30028), August 4, 1986.

5. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," Regulatory Guide 1.175, August 1998.[3]

6. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," Regulatory Guide 1.176, August 1998.[3]

7. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," Regulatory Guide 1.177, August 1998.[3]

8. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping," Regulatory Guide 1.178, September 1998.[3]

9. W.T. Pratt et al., "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," NUREG/CR-6595, January 1999.[2]

10. USNRC, “Addressing PRA Quality in Risk-Informed Activities,” SECY-00-0162, July 28, 2000.[1]

11. G. Apostolakis and S. Kaplan, "Pitfalls in Risk Calculations," *Reliability Engineering*, Vol. 2, pages 135-145, 1981.


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[1] USNRC SECY papers are available electronically on the NRC’s web page at <www.nrc.gov> in the Electronic Reading Room under Commission Documents.

[2] Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; (telephone (703)487-4650; <http://www.ntis.gov/ordernow>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR’s mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; email is PDR@NRC.GOV.

[3] Requests for single copies of draft or active regulatory guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301)415-2289; email <DISTRIBUTION@NRC.GOV>. Electronic copies are available on the NRC;s web page at <www.nrc.gov> in the Electronic Reading Room under Document Collections.

12. Nuclear Energy Institute, “Steam Generator Program Guidelines,” NEI Report 97-06, Revision 1, January 2001.[4]

13. A. Mosleh et al., "Procedures for Treating Common Cause Failures in Safety and Reliability Studies," NUREG/CR-4780, Vol. 2, January 1989.[2]

14. USNRC, "Quality Assurance Program Requirements," Regulatory Guide 1.33, Revision 2, February 1978.[3]

[4] Copies may be purchased from the Nuclear Energy Institute

# BIBLIOGRAPHY


Apostolakis, G.A., "Probability and Risk Assessment: The Subjectivist Viewpoint and Some Suggestions," *Nuclear Safety*, 19(3), pages 305-315, 1978.

Bohn, M.P., T.A. Wheeler, G.W. Parry, "Approaches to Uncertainty Analysis in Probabilistic Risk Assessment," NUREG/CR-4836, USNRC, January 1988.[1]

Hickman, J.W., "PRA Procedures Guide," NUREG/CR-2300, USNRC, January 1983.[1]

Kaplan, S., and B.J. Garrick, "On the Quantitative Definition of Risk," *Risk Analysis*, Vol. 1, pages 11-28, March 1981.

Mosleh, A., et al., "Proceedings of Workshop I in Advanced Topics in Risk and Reliability Analysis, Model Uncertainty: Its Characterization and Quantification" (held in Annapolis, Maryland, October 20-22, 1993), USNRC, NUREG/CP-0138, October 1994.[1]

Parry, G.W., and P.W. Winter, "Characterization and Evaluation of Uncertainty in Probabilistic Risk Analysis," *Nuclear Safety*, 22(1), pages 28-42, 1981.

*Reliability Engineering and System Safety* (Special Issue on the Meaning of Probability in Probabilistic Safety Assessment), Vol. 23, 1988.

*Reliability Engineering and System Safet*y (Special Issue on Treatment of Aleatory and Epistemic Uncertainty), Vol. 54, nos. 2 and 3, November/December 1996.

USNRC, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," NUREG-1150, Vol. 3, January 1991.[1]

USNRC, "A Review of NRC Staff Uses of Probabilistic Risk Assessment," NUREG-1489, Appendix C.6, March 1994.[1]


[1] Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; (telephone (703)487-4650; <http://www.ntis.gov/ordernow>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; email is PDR@NRC.GOV.

# APPENDIX A

## USE OF RISK-IMPORTANCE MEASURES TO CATEGORIZE STRUCTURES, SYSTEMS, AND COMPONENTS WITH RESPECT TO SAFETY SIGNIFICANCE

### INTRODUCTION

For several of the proposed applications of the risk-informed regulation process, one of the principal activities is the categorization of structures, systems, and components (SSCs) and human actions according to safety significance. The purpose of this appendix is to discuss one way that this categorization may be performed to be consistent with Principle 4 and the expectations discussed in Section 2.1 of Regulatory Guide 1.174.

Safety significance of an SSC can be thought of as being related to the role the SSC plays in preventing the occurrence of the undesired end state. Thus the position adopted in this regulatory guide is that all the SSCs and human actions considered when constructing the PRA model (including those that do not necessarily appear in the final quantified model, because they have been screened initially, assumed to be inherently reliable, or have been truncated from the solution of the model) have the potential to be safety significant since they play a role in preventing core damage.

In establishing the categorization, it is important to recognize the purpose behind the categorization, which is, generally, to sort the SSCs and human actions into groups such as those for which some relaxation of requirements is proposed, and those for which no such change is proposed. It is the proposed application that is the motivation for the categorization, and it is the potential impact of the application on the particular SSCs and human actions and on the measures of risk that ultimately determines which of the SSCs and human actions must be regarded as safety significant within the context of the application. This impact on overall risk should be evaluated in light of the principles and decision criteria identified in this guide. Thus, the most appropriate way to address the categorization is through a requantification of the risk measures.

However, the feasibility of performing such risk quantification has been questioned when a method for evaluating the impact of the change on SSC unavailability is not available for those applications. An acceptable alternative to requantification of risk is for the licensee to perform the categorization of the SSCs and human actions in an integrated manner, making use of an analytical technique, based on the use of PRA importance measures, as input. This appendix discusses the technical issues associated with the use of PRA importance measures.

### TECHNICAL ISSUES ASSOCIATED WITH THE USE OF IMPORTANCE MEASURES

In the implementation of the Maintenance Rule and in industry guides for risk-informed applications (for example, the "PSA Applications Guide"[1]), the Fussell-Vesely Importance, Risk Reduction Worth, and Risk Achievement Worth are the most commonly identified measures in the

[1] D. True et al., "PSA Applications Guide," Electric Power Research Institute, TR-105396, August 1995.

relative risk ranking of SSCs. However, in the use of these importance measures for risk-informed applications, there are several issues that should be addressed. Most of the issues are related to technical problems that can be resolved by the use of sensitivity studies or by appropriate quantification techniques. These issues are discussed in detail below. In addition, there are two issues, namely (1) that risk rankings apply only to individual contributions and not to combinations or sets of contributors, and (2) that risk rankings are not necessarily related to the risk changes that result from those contributor changes; the licensee should be aware of these issues and ensure that they have been addressed adequately. When performed and interpreted correctly, component-level importance measures can provide valuable input to the licensee.

Risk-ranking results from a PRA can be affected by many factors, the most important being model assumptions and techniques (e.g., for modeling of human reliability or common cause failures), the data used, or the success criteria chosen. The licensee should therefore make sure that the PRA is technically acceptable.

In addition to the use of a technically acceptable PRA, the robustness of categorization results should also be demonstrated for conditions and parameters that might not be addressed in the base PRA. Therefore, when importance measures are used to group components or human actions as low-safety-significant contributors, the information to be provided to the analysts performing qualitative categorization should include sensitivity studies or other evaluations to demonstrate the sensitivity of the importance results to the important PRA modeling techniques, assumptions, and data. Issues that should be considered and addressed are listed here.

**Truncation Limit:** The licensee should determine that the truncation limit has been set low enough so that the truncated set of minimal cutsets contains all the significant contributors and their logical combinations for the application in question and is low enough to capture at least 95% of the core damage frequency (CDF). Depending on the PRA level of detail (module level, component level, or piece-part level), this may translate into a truncation limit from $10^{-12}$ to $10^{-8}$ per reactor year. In addition, the truncated set of minimal cutsets should be determined to contain the important application-specific contributors and their logical combinations.

**Risk Metrics:** The licensee should ensure that risk in terms of both CDF and large early-release frequency (LERF) is considered in the ranking process.

**Completeness of Risk Model:** The licensee should ensure that the PRA model is sufficiently complete to address all important modes of operation for the SSCs being analyzed. Safety-significant contributions from internal events, external events, and shutdown and low-power initiators should be considered by using PRA or other engineering analyses.

**Sensitivity Analysis for Component Data Uncertainties:** The sensitivity of component categorizations to uncertainties in the parameter values should be addressed by the licensee. Licensees should be satisfied that SSC categorization is not affected by data uncertainties.

**Sensitivity Analysis for Common Cause Failures:** CCFs are modeled in PRAs to account for dependent failures of redundant components within a system. The licensee should determine that the safety-significant categorization has taken into account the combined effect of associated basic

PRA events, such as failure to start and failure to run, including indirect contributions through associated CCF event probabilities. CCF probabilities can affect PRA results by enhancing or obscuring the importance of components. A component may be ranked as a high risk contributor mainly because of its contribution to CCFs, or a component may be ranked as a low risk contributor mainly because it has negligible or no contribution to CCFs.

**Sensitivity Analysis for Recovery Actions:** PRAs typically model recovery actions, especially for dominant accident sequences. Quantification of recovery actions typically depends on the time available for diagnosis and for performing the action, as well as the training, procedures, and knowledge of operators. There is a certain degree of subjectivity involved in estimating the success probability for the recovery actions. The concerns in this case stem from situations in which very high success probabilities are assigned to a sequence, resulting in related components being ranked as low risk contributors. Furthermore, it is not desirable for the categorization of SSCs to be affected by recovery actions that sometimes are only modeled for the dominant scenarios. Sensitivity analyses can be used to show how the SSC categorization would change if all recovery actions were removed. The licensee should ensure that the categorization has not been unduly affected by the modeling of recovery actions.

**Multiple Component Considerations:** As discussed previously, importance measures are typically evaluated on an individual SSC or human action basis. One potential concern raised by this is that single-event importance measures have the potential to dismiss all the elements of a system or group despite the fact that the system or group has a high importance when taken as a whole. (Conversely, there may be grounds for screening out groups of SSCs, owing to the unimportance of the systems of which they are elements.) There are two potential approaches to addressing the multiple component issue. The first is to define suitable measures of system or group importance. The second is to choose appropriate criteria for categorization based on component-level importance measures. In both cases, it will be necessary for the licensee to demonstrate that the cumulative impact of the change has been adequately addressed.

While there are no widely accepted definitions of system or group importance measures, if any are proposed the licensee should make sure that the measures are capturing the impact of changes to the group in a logical way. As an example of the issues that arise, consider the following. For front-line systems, one possibility would be to define a Fussell-Vesely type measure of system importance as the sum of the frequencies of sequences involving failure of that system, divided by the sum of all sequence frequencies. Such a measure would need to be interpreted carefully if the numerator included contributions from failures of that system caused by support systems. Similarly, a Birnbaum-like measure could be defined by quantifying sequences involving the system, conditional on its failure, and summing up those quantities. This would provide a measure of how often the system is critical. However, again the support systems make the situation more complex. To take a two-division plant as an example, front-line failures can occur as a result of failure of support division A in conjunction with failure of front-line division B. Working with a figure of merit based on "total failure of support system" would miss contributions of this type.

In the absence of appropriately defined group-level importance measures, reliance must be on a qualitative categorization by the licensee, as part of the integrated decisionmaking process, to make the appropriate determination.

**Relationship of Importance Measures to Risk Changes:** Importance measures do not directly relate to changes in risk. Instead, the risk impact is indirectly reflected in the choice of the value of the measure used to determine whether an SSC should be classified as being of high and low safety significance. This is a concern whether importances are evaluated at the component or at the group level. The PSA Applications Guide[1] suggested values of Fussell-Vesely importance of 0.05 at the system level and 0.005 at the component level, for example. However, the criteria for categorization into low and high significance should be related to the acceptance criteria for changes in CDF and LERF. This implies that the criteria should be a function of the base case CDF and LERF rather than being fixed for all plants. Thus the licensee should demonstrate how the chosen criteria are related to, and conform with, the acceptance guidelines described in this document. If component-level criteria are used, they should be established taking into account that the allowable risk increase associated with the change should be based on simultaneous changes to all members of the category.

**SSCs Not Included in the Final Quantified Cutset Solution:** Importance measures based on the quantified cutsets will not factor in those SSCs that have either been truncated or were not included in the fault tree models because they were screened on the basis of high reliability. SSCs that have been screened because their credible failure modes would not fail the system function can be argued to be unimportant. The licensee must make sure that these SSCs are considered.

## REGULATORY ANALYSIS

A draft regulatory analysis was published with the draft of this guide when it was originally published for public comment (Task DG-1061, June 1997). No changes were necessary to the regulatory analysis, so a separate regulatory analysis has not been prepared for this Revision 1 to Regulatory Guide 1.174. A copy of the draft regulatory analysis is available for inspection or copying for a fee in the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or 1-(800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.