U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

May 2012
Division 1

DRAFT REGULATORY GUIDE

Contact: A. Gilbertson
(301) 251-7592

DRAFT REGULATORY GUIDE DG-1285

(Proposed Revision 3 to Regulatory Guide 1.174, dated May 2011)

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

A. INTRODUCTION

The U.S. Nuclear Regulatory Commission's (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. A description of current risk-informed initiatives may be found in (1) recent updates to the NRC staff's Risk-Informed and Performance-Based Plan (RPP) formerly known as the Risk-Informed Regulation Implementation Plan (Ref. 2), and (2) the agency Internet site at http://www.nrc.gov/about-nrc/regulatory/risk-informed.html.

One significant activity undertaken in response to the policy statement is the use of 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 to support licensee requests for changes to a plant's LB, as in requests for license amendments and technical specification changes under Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit," through 50.92, "Issuance of Amendment." 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, "Changes, Tests, and Experiments" and 10 CFR 52 Appendices, Section VIII, "Processes for Changes and Departures").

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.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by June 29, 2012.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/; and the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML12012A006. The regulatory analysis may be found in ADAMS under Accession No. ML12013A089.

The staff may evaluate licensee-initiated LB change requests that go beyond current staff positions using traditional engineering analyses as well as the risk-informed approach set forth in this regulatory guide. The staff may request a licensee to submit supplemental risk information if such information is not submitted by the licensee. If the licensee does not provide risk information on the proposed LB change, 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 will review these LB changes by considering engineering issues and applying risk insights. Licensees that 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.

Appendix D to Section 19.2 of the Standard Review Plan (SRP) (Ref. 3) provides the staff with additional guidance regarding the circumstances and process under which NRC staff reviewers would request and use risk information in the review of nonrisk-informed license amendment requests.

The guidance provided in this regulatory guide does not preclude other approaches for requesting changes to the LB. Rather, the staff intends for this regulatory guide 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.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that the Office of Management and Budget (OMB) approved under OMB control number 3150-0011. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number. This regulatory guide is a rule as designated in the Congressional Review Act (5 U.S.C. 801-808). However, OMB has not found it to be a major rule as designated in the Congressional Review Act.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guides and standards constituting a high level of safety for protecting people and the environment. IAEA safety guides present international good practices and increasingly reflects best practices to help users striving to achieve high levels of safety. Pertinent to this regulatory guide, IAEA Safety Guide SSG-3, "Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," issued April 2010, and SSG-4, "Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," issued May 2010 address probabilistic risk assessment concepts. The safety guides provide recommendations for performing or managing a probabilistic safety assessment project for nuclear power plants and using it to support safe design and operation. This regulatory guide discusses some of the same principles with respect to changes to a plant's licensing basis.

B. DISCUSSION

Reason for Change (or Issue)

The NRC staff is revising this guide to update the defense-in-depth language using precise language to assure the defense-in-depth philosophy is interpreted and implemented consistently.

Background

Both the NRC and the nuclear industry recognize 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 for 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: (1) foremost, through safety decisionmaking enhanced by the use of PRA insights, (2) through more efficient use of agency resources, and (3) 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 RPP (Ref. 2) with its updates, and on the agency's public Internet site (see Part A of this regulatory guide) 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 (CDFs) 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 percent) of other risks to which the public is exposed. The acceptance guidelines defined in this regulatory guide (in Section 2.4) are based on subsidiary objectives derived from the safety goals and their QHOs.

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 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. Additional or revised guidance is provided for new reactors (e.g., advanced light-water reactors) licensed under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants.

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 to 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 this regulatory guide, the NRC has chosen a framework that would permit only small increases in risk and only when it is reasonably assured, among other things, that sufficient defense-in-depth and sufficient margins are maintained. This framework was 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.

Relationship to Other Guidance Documents

Directly relevant to this regulatory guide is the SRP (Ref. 3) designed to guide the NRC staff evaluations of licensee requests for changes to the LB that apply risk insights, as well as guidance developed in selected application-specific regulatory guides and the corresponding SRP chapters. The NRC has developed related regulatory guides on inservice testing, inservice inspection and technical specifications (Refs. 5, 7, and 8). The agency withdrew a regulatory guide covering graded quality assurance (Ref. 6), which was superseded by Regulatory Guide 1.201, Trial Use, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," issued May 2006 (Ref. 9). An NRC contractor report (Ref. 10) is also available that provides a simple screening method for assessing one measure used in the regulatory guide—large early release frequency (LERF). 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.

This regulatory guide also invokes Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." (Ref. 11) Regulatory Guide 1.200 provides the necessary guidance for determining the technical adequacy of the base PRA. Figure 1 (taken from Regulatory Guide 1.200) shows the relationship of this regulatory guide to risk-informed activities, other application-specific guidance, Regulatory Guide 1.200, consensus PRA standards, and industry programs.

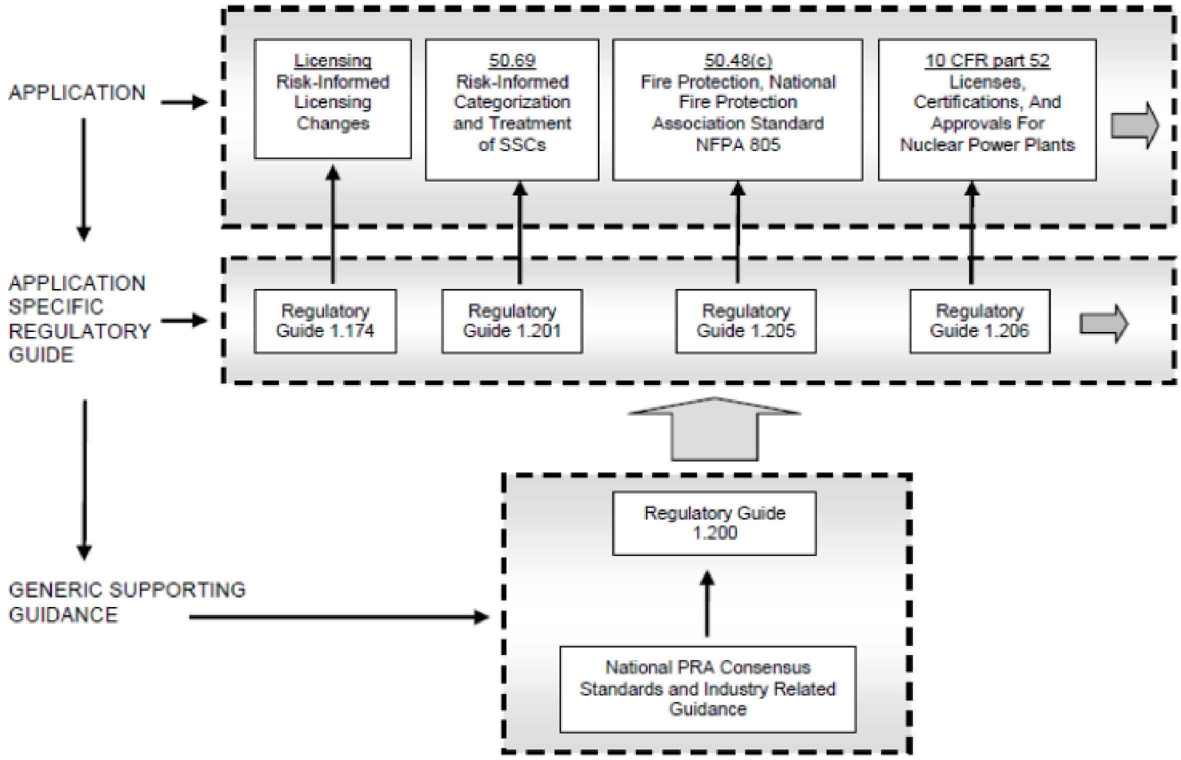

Figure 1 Relationship of Regulatory Guide 1.174 to other risk-informed guidance

C. STAFF REGULATORY GUIDANCE

In its approval of the policy statement on the use of PRA methods in nuclear regulatory activities (Ref. 1), the Commission stated its 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 include the following:

1. The proposed change meets the current regulations unless it is explicitly related to a requested exemption (i.e., a specific exemption under 10 CFR 50.12, "Specific Exemptions").

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

3. The proposed change maintains sufficient safety margins.

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

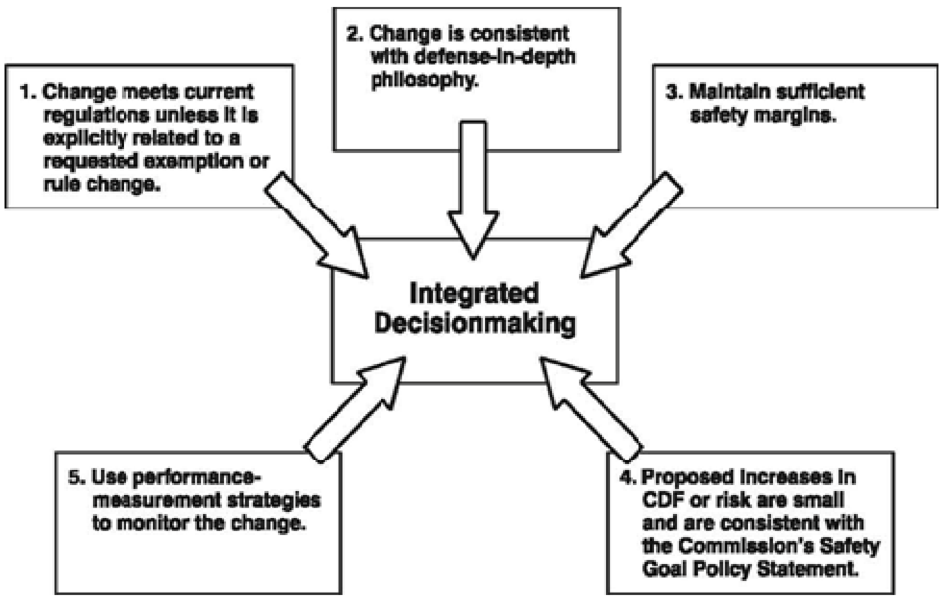

Figure 2 Principles of risk-informed integrated decisionmaking

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

- 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 in which 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 in which requirements should be increased as well as those in which 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 (1) be appropriate for the nature and scope of the change, (2) be based on the as-built and as-operated and maintained plant, and (3) reflect operating experience at the plant.

---

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

- The plant-specific PRA supporting the licensee's proposals has been demonstrated to be of sufficient technical adequacy.

- Appropriate consideration of uncertainty is given in the analyses and interpretation of findings, including use of a program of monitoring, feedback, and corrective action to address key sources of uncertainty. NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," (Ref. 12) provides further guidance.

- The use of CDF and 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, risk increase and risk decrease (if available), 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 Figure 3 presents graphically, supports the NRC's decisionmaking process. This approach is not sequential in nature; rather it is iterative.

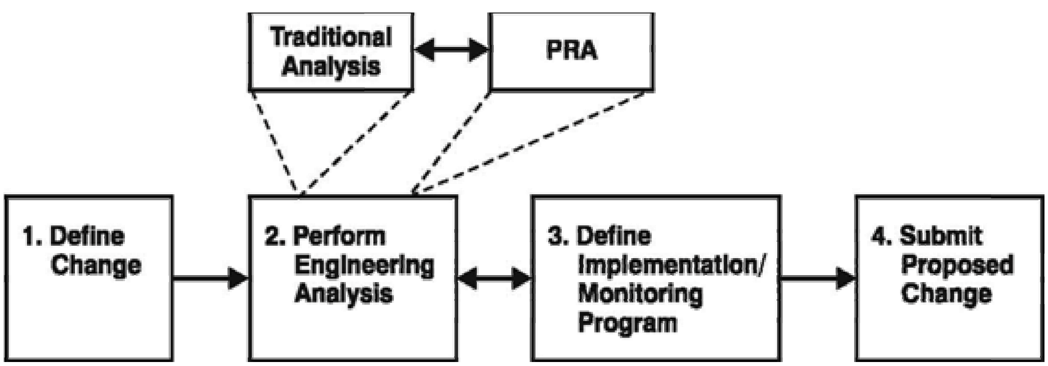

Figure 3 Principal elements of risk-informed, plant-specific decisionmaking

---

[3] In this context, LERF is being used as a surrogate for the early fatality QHO. It is defined as the sum of the frequencies of those accidents leading to rapid, unmitigated release of airborne fission products from the containment to the environment occurring before the effective implementation of offsite emergency response and protective actions such that there is the potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure 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.

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, 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.

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 (i.e., a specific exemption under 10 CFR 50.12).

1.1 <u>Combined Change Requests</u>

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

1. CCRs in which any individual change increases risk; or
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.

1.2 <u>Guidelines for Developing Combined Change Requests</u>

The changes that make up a CCR should be related to one another (e.g., they affect the same single system or activity, they affect the same safety function or accident sequence or group of sequences, or they are the same type, such as 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 Part C 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 2.4 of this guide should be assessed.

In implementing CCRs in the first category, the risk from significant accident sequences will not be increased and the frequencies of the lower ranked contributors will not be increased so that they become significant contributors to risk. No significant new sequences or cutsets should 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 should also address the impact on the previously approved CCR. Specifically, the licensee should address whether the proposed modification would cause the previously approved CCR to become unacceptable. If this is the case, the submittal should address the actions the licensee is taking with respect to the previously approved CCR.

2. Element 2: Perform Engineering Analysis

The scope, level of detail, and technical adequacy of the engineering analyses conducted to justify any proposed LB change should be appropriate for the nature and scope of the proposed change. The licensee should appropriately consider uncertainty in the analysis and interpretation of findings. The licensee should use judgment on the complexity and difficulty of implementing the proposed LB change in deciding 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 should show that it has met the principles set forth in Part C of this regulatory guide 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 special treatment requirements commensurate with the safety significance of equipment under 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Plants." Like other applications, the staff's review of LB change requests for applications involving safety categorization will be in accordance with the acceptance guidelines associated with each key principle presented in this regulatory guide, unless the licensee proposes alternative, equivalent guidelines. Since risk-importance measures are often used in such categorizations, Appendix A to this regulatory guide provides guidance on their use. Other application-specific guidance documents address guidelines associated with the adequacy of programs (in this example, special treatment requirements) 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 should evaluate the proposed LB change with regard to the principles of maintaining adequate defense-in-depth, maintaining sufficient safety margins, and ensuring that proposed increases in CDF and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement (Ref. 4).

2.1 **Evaluation of Defense-in-Depth Attributes and Safety Margins**

One aspect of the engineering evaluation is to show that the proposed change does not compromise the fundamental safety principles on which the plant design was based. Design-basis accidents (DBAs) evaluated using the fundamental principles of the philosophy of defense-in-depth and maintaining sufficient safety margins play a central role in the design of nuclear power plants. 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 of physical properties and operating characteristics 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 also influence plant design and operation. The licensee's proposed LB change may affect margins and defenses incorporated into the current plant design; therefore, the licensee should reevaluate margins and defense to support a requested LB change. As part of this evaluation, the impact of the proposed LB change on the functional capability, reliability, and availability of affected equipment should be determined. The plant's LB identified in the FSAR is the reference point for judging whether a proposed change adversely affects defense-in-depth or safety margins.

2.1.1 ***Defense-in-Depth***

The engineering evaluation should evaluate whether the impact of the proposed LB change (individual and cumulative) is consistent with the defense-in-depth philosophy. In this regard, the intent of this 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. Defense-in-depth is an element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

At a high level, there are three layers of defense against the consequences of an event at a nuclear facility. The three layers are (1) protection to prevent accidents from occurring, (2) mitigation of accidents if they occur, and (3) emergency preparedness to minimize the public health consequences of releases if they occur. An important element of the three layers is that a reasonable balance should be preserved among them. Another major aspect of defense-in-depth is maintaining multiple barriers to the release of fission products. While it could be reasoned that multiple fission product barriers represent one approach to implementing the three high-level layers of defense-in-depth, the use of barriers is so fundamental to this philosophy that it warrants its own discussion.

The sections below discuss the three high-level layers of defense-in-depth, followed by a discussion of fission product barriers. A discussion follows of some factors that licensees should consider when assessing whether a proposed change to the plant is consistent with the three layers and the multiple-barrier philosophy.

2.1.1.1 Preserving Balance Among the Three Layers of Defense-in-Depth

A reasonable balance of these layers (i.e., preventing accidents, mitigating accidents, and emergency preparedness) helps to ensure an apportionment of the plant's capabilities between limiting disturbances to the plant and mitigating their consequences. "Balance" is not meant to imply an equal apportionment of capabilities. A reasonable balance is preserved if the proposed plant change does not significantly reduce the effectiveness of a layer that exists in the plant design before the proposed change. The NRC recognizes that there may be aspects of a plant's design that may cause one of the three layers to be adversely affected. For these situations, the balance between the other two layers becomes especially important when evaluating the impact of a proposed change to the LB and its impact on defense-in-depth.

2.1.1.2 Preserving Multiple Fission Product Barriers

The plant's LB includes fission product barriers and engineered structures, systems, and components (SSCs) that support or maintain those barriers. These barriers, as exemplified by current reactors, are generally considered to be the fuel elements' cladding, the reactor coolant system pressure boundary, and the containment systems and structure. Adverse conditions created during reactor accidents (e.g., high temperature, high pressure) can challenge the integrity of barriers. Consequently, the concept of multiple barriers provides for separate means to contain and mitigate fission products. The intent of preserving multiple barriers may be adversely affected if the proposed plant change reduces the effectiveness of any of the barriers. The licensee should evaluate the impact of the proposed change on the fission product barriers and supporting systems and consider any cause and effect relationship between the barrier and the aspect of the plant proposed to be changed.

2.1.1.3 Factors To Consider When Evaluating the Impact of a Change on Defense-in-Depth

When evaluating the impact of a proposed plant change on the three high-level layers (Section 2.1.1.1 above) and the multiple fission product barriers (Section 2.1.1.2 above) of defense-in-depth, the licensee should consider the following factors:

- programmatic activities as compensatory measures;
- system redundancy, independence, and diversity;
- potential for common-cause failure (CCF);
- reliance on plant operators; and
- intent of the plant's design criteria.

These factors are not meant to be a comprehensive list, but are intended to help the licensee assess how the proposed change could affect one of the three layers of defense or one of the multiple barriers. Each of the factors is discussed in greater detail below. The examples provided are intended to illustrate the specific factor being discussed and are not meant to illustrate the actual process for assessing a risk-informed change to a plant's LB.

1. Avoid overreliance on programmatic activities as compensatory measures associated with the change to the LB.

   Programmatic activities are administrative controls, not engineered safety features. Although programmatic activities are used to ensure safety functions, the regulations demonstrate a definite preference for engineered safety features to mitigate DBAs. The licensee should adhere to this preference and, therefore, should assess whether the proposed change would increase the need for programmatic activities to compensate for the lack of engineering features. If the change employs compensatory measures, the licensee should justify that reliance on these measures is not excessive. Use of compensatory measures may be considered overreliance when a programmatic activity is substituted for an engineered means of performing a safety function, or failure of the programmatic activity could prevent an engineered safety feature from performing its intended function. Moreover, overreliance on a programmatic activity can potentially result in significant reduction in the effectiveness of one of the defense-in-depth layers that exists in the plant design before the proposed change, or it may lessen the effectiveness of one of the fission product barriers. The licensee should evaluate the impact to confirm that a reasonable balance of the defense-in-depth layers is preserved and that multiple barriers to contain potential fission product releases are maintained.

The NRC also recognizes that programmatic activities used as compensatory measures are generally associated with temporary conditions. For these situations, the licensee should demonstrate that the plant condition requiring such compensatory measures would occur at a sufficiently low frequency.

<u>Examples</u>:

- The proposed plant change involves the removal of fire doors with an associated compensatory measure of placing a fire watch. The compensatory measure as a permanent change to the plant may be considered to be over-reliant on a programmatic activity. However, if the compensatory measure were implemented, for example, on a temporary basis (e.g., until the next fuel reload or other appropriate interval), the licensee may be able to justify such a change.

- The proposed change involves a power uprate that results in higher temperatures of the fluid available to the suction of the containment heat removal pumps. The licensee proposes to credit containment accident pressure in its analysis of the net positive suction head (NPSH) available to these pumps. However, it is determined that this pressure may not be available if nonsafety-related containment fan coolers continue to run after an accident. The licensee proposes to write a new procedure to direct operators to secure these containment fan coolers in the event of a reactor accident instead of designing a trip circuit to perform this function automatically. This procedure could be considered overreliance on a programmatic activity. However, if it can be demonstrated, for example, that this additional operator action is reliable and feasible, does not overburden the operators or adversely affect their ability to respond to an accident, does not otherwise affect plant safety, the licensee may be able to justify such a change.

- The proposed change involves increasing the inspection interval for the reactor vessel weld from 10 to 20 years. The licensee argues that this change in interval does not change the reactor vessel design or any of the plant's design parameters and is therefore consistent with the philosophy of defense-in-depth. The increase in inspection interval could be considered overreliance on a programmatic activity because any existing flaws that were missed during the inspection would have a longer time in which to grow. Thus, increasing the inspection interval could change the robustness of the reactor vessel, albeit very slightly. However, if the extension of the interval were accompanied by appropriate technical evaluations and an improved, industrywide monitoring program, the licensee might be able to justify that the proposed change is not an overreliance, given the slight impact on the robustness of the reactor vessel.

2. Preserve sufficient system redundancy, independence, and diversity.

An important aspect of ensuring safety functions is to guard against adversely affecting plant features that provide system redundancy, independence, or diversity. “Safety functions” are those that ensure the integrity of the reactor coolant pressure boundary, the ability to shut down the reactor and maintain it in a safe-shutdown condition, or the ability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to those referred to in 10 CFR Part 100, “Reactor site Criteria.” A proposed risk-informed change should also consider both safety-related and nonsafety-related SSCs that are important to core damage or large early release. Redundancy enables the failure or unavailability of at least one set of equipment to be tolerated without loss of function. Independence among systems is often achieved by the use of physical separation or physical protection. Diversity is applied to redundant systems or components that perform the same function by incorporating different attributes, such as different principles of operation, different physical variables, different conditions of operation, or production by different manufacturers.

A substantial reduction in the ability to accomplish a safety function is not consistent with the defense-in-depth philosophy. A safety function may be compromised (and therefore system redundancy, independence, and diversity not preserved) when a proposed change would introduce new dependencies among plant equipment or would defeat one of the plant features that provides system redundancy, independence, or diversity. The introduction of new dependencies could reduce the level of redundancy, independence, or diversity for fulfilling a safety function. One form of dependency, the possibility of CCFs, is addressed in more detail under the next factor. Reduction in system redundancy, independence, or diversity can potentially result in significant reduction in the effectiveness of one of the defense-in-depth layers that exists in the plant design before the proposed change or may reduce the effectiveness of one of the fission product barriers.

The licensee should demonstrate that new dependencies that could adversely affect system redundancy, independence, or diversity have not been introduced, or that the change itself is not defeating one of the plant features that provide system redundancy, independence, or diversity. A licensee could use risk assessment techniques to identify any increase in system dependency or risk importance resulting from the proposed change.

Examples:

– The proposed plant change involves extending the Technical Specification completion time for a risk-significant system. While the system is out of service, there may be no redundancy for the function that the system provides. Removing the redundant train from the plant entirely would not be consistent with this factor of defense-in-depth. However, if it can be demonstrated, for example, that the proposed completion time is short enough to meet the risk acceptance guidelines in Regulatory Guides (RG) 1.174 and RG 1.177 (because, perhaps, a nonsafety system that can perform the safety function is operable and available), that adequate margins are maintained, and that other principles of risk-informed regulation given earlier in this section are met, the licensee may be able to justify such a change.

– The proposed change is a power uprate that results in higher temperatures of the fluid available to the suction of the emergency core cooling system (ECCS) pumps. The licensee proposes to credit containment accident pressure in its analysis of the NPSH available to these pumps. This change results in a dependency between two of the fission product barriers: if the containment fails to hold pressure, the ECCS pumps may fail due to lack of NPSH, resulting in damage to the fuel cladding. This could be interpreted as an unacceptable reduction in the effectiveness of the multiple fission product barriers.

However, if the licensee can demonstrate, for example, that the ECCS pumps were sufficiently robust to operate with less than the minimum NPSH specified, such that the pumps could fulfill their intended function even without crediting containment accident pressure, the licensee might be able to justify such a change.

– The proposed change to a passive plant system involves a Tier 1 (as defined in 10 CFR Part 52) change to a system categorized under the regulatory treatment of nonsafety systems (RTNSS) process. Such RTNSS systems are active systems that are relied on for defense-in-depth and are necessary to meet passive advanced light-water reactor (ALWR) plant safety and investment protection goals. Removing such a system from the administrative controls on system availability for investment protection or significantly increasing the completion times for restoring availability may not be consistent with the defense-in-depth philosophy. However, if it can be demonstrated, for example, that the newly proposed completion time is short enough to meet the risk acceptance guidelines in RG 1.174, that adequate margins are maintained, and that the other principles of risk-informed regulation given earlier in this section are also met, the licensee may be able to justify such a change.

3. Preserve adequate defense against potential CCFs and assess the potential for the introduction of new CCF mechanisms.

An important aspect of ensuring safety functions is to guard against CCF. Failure of several devices or components to function may occur as a result of a single specific event or cause. Such failures may simultaneously affect several different items important to safety. The event or cause may be a design deficiency, a manufacturing deficiency, an operating or maintenance error, a natural phenomenon, a human-induced event, or an unintended cascading effect from any other operation or failure within the plant. A CCF can result in the failure or degradation of a safety function, thereby significantly reducing the effectiveness of one of the defense-in-depth layers that exists in the plant design before the proposed change or lessening the effectiveness of one of the fission product barriers.

The licensee should evaluate the proposed change to determine whether it increases the potential for events or causes that would be a CCF. The licensee should also evaluate the proposed change to determine whether new CCF mechanisms could be introduced.

Examples:

– The proposed change is a new corrosion-resistant material for one component of the plant's seawater pumps. There may be uncertainty regarding how this new material will perform with respect to the other materials in the pump, creating the potential for new failure mechanisms (e.g., galvanic corrosion). Changing this part in all service water pumps within a short time could create a CCF mechanism, and therefore, defenses against CCF would not be preserved. However, a licensee might commit to changing the material in only one pump until operating experience indicates that new failure mechanisms have not been introduced. Using a phased implementation approach might allow the licensee to justify such a change.

– The proposed change is to use new, "improved" grease in the motor-operated valves (MOVs) at the plant. Maintenance procedures would be changed to specify use of the new grease. There may be uncertainty regarding the potential for new failure modes as a result of the new grease, and these failures could occur in all MOVs where the new grease is applied. This change could affect this element of defense-in-depth. However, a licensee might commit to changing to the new grease on only one train of equipment until operating experience indicates that new failure mechanisms have not been introduced. Similar to the example above, such a phased implementation approach might allow the licensee to justify such a change.

- The proposed change is the relaxation of special treatment requirements on components that are of low safety significance. Because the treatment requirements would be changed for all similar components, there may be new failure mechanisms that would increase the probability of CCF of these similar components. An increased CCF probability could invalidate the assumptions underlying the categorization process (e.g., the components might not be of low safety significance if this new CCF mechanism were taken into account). However, if the licensee demonstrated that the categorization as "low safety significance" was relatively insensitive to CCF probability, for example, the change might be justified as preserving defenses against CCF.

4. Preserve sufficient defense against human error.

Human errors include (1) the failure of operators to perform the actions necessary to operate the plant or respond to off-normal conditions and accidents, (2) errors committed during maintenance, and (3) operators performing an incorrect action. The plant includes defenses to prevent the occurrence of such events and errors. These defenses generally involve the use of procedures, training, and human engineering. These defenses are preserved if the proposed plant change does not increase the potential for human errors that can lead directly to a beyond-design-basis event or affect the ability of operators to place the plant in a safe-shutdown condition or carry out emergency operating procedures correctly. Human errors can result in the degradation or failure of a system to perform its function, thereby significantly reducing the effectiveness of one of the defense-in-depth layers or one of the fission product barriers.

The licensee should assess whether the proposed change would create new operator actions, increase the burden on operators in responding to events, or increase the probability of existing operator errors. The licensee should consider whether the change creates new situations that are likely to cause errors, not only for operators, but for maintenance personnel and other plant staff.

<u>Examples</u>:

- The proposed change results in an operator action that is necessary in the long term, but also counterintuitive, thereby potentially increasing the likelihood that the operator will fail to properly perform the action. In this situation, defenses against human error may not be preserved. However, if it can be demonstrated, for example, that operators have adequate indications, available time, and training to provide a high confidence that the action would be performed when needed, the licensee may be able to justify such a change.

- The proposed plant change involves a change to the loading of spent fuel in which a single human error in loading would lead to criticality. In this situation, defenses against human errors would not be preserved. However, if it can be demonstrated, for example, that the implementation of a different, more reliable method of loading fuel in the spent fuel pool would prevent this human error, the licensee may be able to justify such a change.

- The proposed plant change involves a Tier 1 (as defined in 10 CFR Part 52) change and redesign of the passive containment venting system for an ALWR that requires operator action for venting. In this situation, defenses against human error may not be preserved. However, if the licensee commits to operator training and demonstrates that the increased training would offset potential errors, the licensee may be able to justify such a change.

5. Maintain the intent of the plant's design criteria.

The plant's design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The plant's design basis includes criteria for evaluating whether a proposed change could adversely affect the defense-in-depth provided in the plant design. When evaluating the effect of the proposed change, the licensee should determine whether the plant's design criteria are affected.

The plant's design criteria define requirements that implement the defense-in-depth philosophy; as a consequence, a compromise to those design criteria can directly result in a significant reduction in the effectiveness of one of the defense-in-depth layers, or may adversely impact the effectiveness of one of the fission product barriers. In evaluating the plant change, the licensee should evaluate the impact on the plant's design criteria to confirm that a reasonable balance of the defense-in-depth layers is preserved and that multiple barriers to contain potential fission products releases are maintained.

Examples:

- The change is to eliminate inservice inspection of reactor vessel welds based on a very low probability of vessel rupture. The design criteria for most plants include a requirement that SSCs important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Inservice inspection of the reactor vessel is an important part of ensuring the continued reliability of the vessel. Moreover, the plant design does not include systems to mitigate reactor vessel rupture. Consequently, vessel rupture is expected to lead to core damage and, ultimately, the potential for damaged fuel outside the vessel, thereby challenging containment integrity. Therefore, elimination of inservice inspection does not maintain this defense-in-depth element. However, if it can be demonstrated, for example, that reduction in inspection frequency maintains the intent of the plant's design basis, the licensee may be able to justify such a change in this manner (i.e., reduction versus elimination).

The discussion of layers of defense, multiple fission product barriers, and the related factors presented above can help focus the licensee's justification that the proposed change maintains the philosophy of defense-in-depth. The five factors presented above are not intended to define how defense-in-depth is implemented in a plant's original design, but to help licensees assess the impact of the proposed change with respect to the three layers of defense-in-depth and the multiple fission product barriers. Other similar factors also may be used if justified by the licensee for the specific proposed change.

In the risk-informed framework, the defense-in-depth element is derived from traditional engineering considerations. It is not intended that the assessment of defense-in-depth be dependent on risk insights arising from probabilistic risk assessment models. However, a comprehensive risk analysis can provide quantitative and qualitative insights regarding the extent to which a proposed change might affect the balance among the levels of defense-in-depth (i.e., balance among preventing accidents, mitigating accidents, and emergency preparedness). Quantitative and qualitative risk insights can also be useful in identifying any adverse impact of a proposed change on the effectiveness of the fission product barriers. Risk information can also help identify how a proposed change could affect programmatic activities; system redundancy, independence, and diversity; CCF; and reliance on operator actions. While defense-in-depth is not itself risk informed, available risk insights should be used to complement the licensee's deterministic assessment regarding how the proposed change might affect the defense-in-depth element of risk-informed regulation.

2.1.2 ***Safety Margin***

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 to be 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, the following are true:

- 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.

The NRC has developed application-specific guidelines reflecting this general guidance which may be found in the application-specific regulatory guides (Refs. 5–9).

2.2 <u>Evaluation of Risk Impact, Including Treatment of Uncertainties</u>

The licensee may use its risk assessment 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 risk assessment (e.g., internal hazards only, at-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 risk assessment, in the form of a PRA (i.e., one appropriate to derive a quantified estimate of the total impact of the proposed LB change) will be necessary to provide adequate justification.[4]

In other applications, calculated risk-importance measures or bounding risk 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 quantitative risk metrics adopted in this regulatory guide are CDF and LERF. There are, however, risk impacts that are not reflected (or are inadequately reflected) by changes to CDF and LERF. Therefore, the impacts of the proposed change on aspects of risk not captured (or inadequately captured)

---

[4] Regulatory Guide 1.200 (Ref. 11) defines a PRA: "For a method or approach to be considered a PRA, the method or approach (1) provides a quantitative assessment of the identified risk in terms of scenarios that result in undesired consequences (e.g., core damage or a large early release) and their frequencies, and (2) is comprised of specific technical elements in performing the quantification." Section 1.2 of Regulatory Guide 1.200 defines the technical elements.

by these metrics should be addressed. For example, changes affecting long-term containment performance would impact radionuclide releases from containment occurring after evacuation and could result in substantial changes to offsite consequences such as latent cancer fatalities. Recognizing that the containment function is an important factor in maintaining the defense-in-depth philosophy (as already described in Section 2.1.1), the impact of the proposed change on those aspects of containment function not addressed in the evaluation of LERF should be addressed in the licensee submittal documentation as described in Section 6.3.

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 adequacy, and which sufficiently represents the as-built and as-operated plant, for the intended application. Section 2.3 of this guide discusses the staff's expectations with respect to the needed PRA's scope, level of detail, technical adequacy, and as-built and as-operated plant representation.

2. PRA results are to be used in this decisionmaking process in two ways: (1) to assess the overall baseline CDF/LERF of the plant and (2) to assess the CDF/LERF impact of the proposed change. Section 2.4 of this guide discusses the acceptance guidelines the staff will use 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 2.5 of this guide provides guidelines on how the uncertainty will be addressed in the decisionmaking process.

The staff will base its decision on the proposed LB change on its independent judgment and review of the entire application.

2.3 **Determining the Acceptability of a Probabilistic Risk Assessment**

A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices. Regulatory Guide 1.200 (Ref. 11) describes one acceptable approach for determining whether the technical adequacy of the PRA, in total or the parts that are used to support an application, is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decisionmaking for light-water reactors.

Specifically, RG 1.200 provides guidance on the following PRA features:

- scope of the PRA
- level of detail
- technical elements and their associated attributes and characteristics
- development, maintenance, and upgrade of a PRA

In addition, RG 1.200 provides guidance for the following:

- the NRC's position on PRA consensus standards and industry PRA peer review program documents,

- demonstration that the baseline PRA (in total or specific parts) used in regulatory applications is of sufficient technical adequacy, and

- documentation of the technical adequacy of the PRA to support a regulatory submittal.

Other approaches may also be acceptable, but may increase the scope of the staff review or result in a lower priority based on the availability of staff resources.

Regulatory Guide 1.200 (Ref. 11) endorses the American Society of Mechanical Engineers/American Nuclear Society (ASME/ANS) PRA standard that addresses PRA for CDF and LERF for internal and external hazard groups at-power (Ref. 14). Other standards for low power and shutdown modes of operation and Level 2 and Level 3 PRAs are under development.[5]

The ASME/ANS PRA standard provides technical supporting requirements in terms of three Capability Categories. The intent of the delineation of the Capability Categories within the supporting requirements is generally that the degree of scope and level of detail, the degree of plant specificity, and the degree of realism increase from Capability Category I to Capability Category III. In general, the staff anticipates that current good practice, i.e., Capability Category II of the ASME/ANS standard, is the level of detail that is adequate for the majority of applications [6]. However, for some applications, Capability Category I may be sufficient for some requirements, whereas for other applications it may be necessary to achieve Capability Category III for specific requirements.

This regulatory guide is intended for a variety of applications, consequently the features constituting the acceptability of a PRA can vary. 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. Moreover, the licensee's risk assessment should include 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. Furthermore, emphasis on the PRA features can be reduced if a proposed change to the LB results in a risk decrease or a change that 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.

2.3.1 *Scope Required to Support an Application*

The assessment of the risk implications in light of the acceptance guidelines discussed in Section 2.4 of this guide requires that all plant operating modes and hazard groups be addressed, however, it is not always necessary to have a PRA of such scope. A qualitative treatment of the missing modes and hazard groups may be sufficient when the licensee can demonstrate that those risk contributions would not affect the decision; that is, they do not alter the results of the comparison with the acceptance guidelines in Section 2.4 of this guide. However, when the risk associated with a particular hazard group or operating mode would affect the decision being made, it is the Commission's policy that, if a staff-endorsed PRA standard exists for that hazard group or operating mode, then the risk will be assessed using a PRA that meets that standard (Ref. 13). Section 2.5 of this guide discusses this further. For additional guidance, see Regulatory Position C.1.1 in Regulatory Guide 1.200 (Ref. 11).

---

[5] The ANS is developing a draft standard for a PRA for low-power and shutdown modes of operation (to be incorporated into the ASME/ANS PRA standard (Ref. 14)), for a Level 2 PRA and for a Level 3 PRA.

[6] Regulatory Guide 1.200 (Ref. 11) defines current good practice as those practices that are generally accepted throughout the industry and have been shown to be technically acceptable in documented analyses or engineering assessments.

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 to only identify the impacted elements.

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 2.6 of this guide. In any case, the licensee should properly account for the effects of the changes on the reliability and unavailability of SSCs or on operator actions. For additional guidance, see Regulatory Position C.1.3 in Regulatory Guide 1.200 (Ref. 11).

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 Part C of this regulatory guide and 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 (ΔCDF or ΔLERF) along the y-axis (Figures 4 and 5). Acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full-scope (including internal and external hazards, at-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 (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 2.5 of this guide.

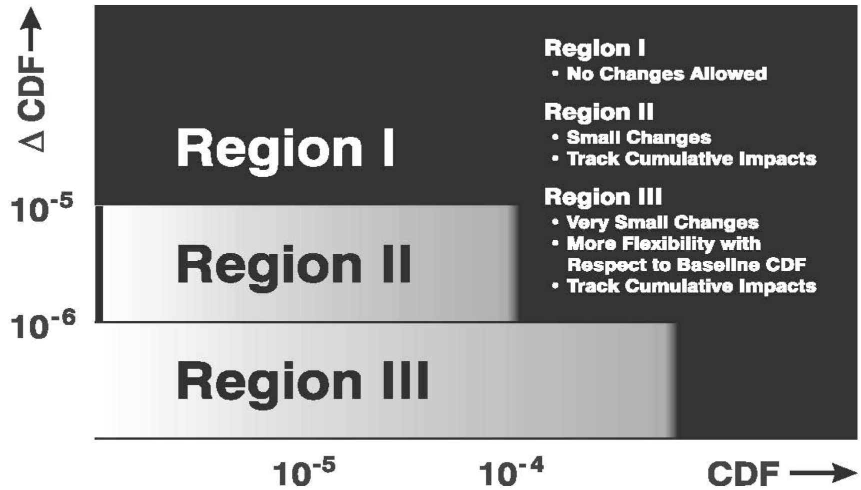

Figure 4 Acceptance guidelines* for core damage frequency

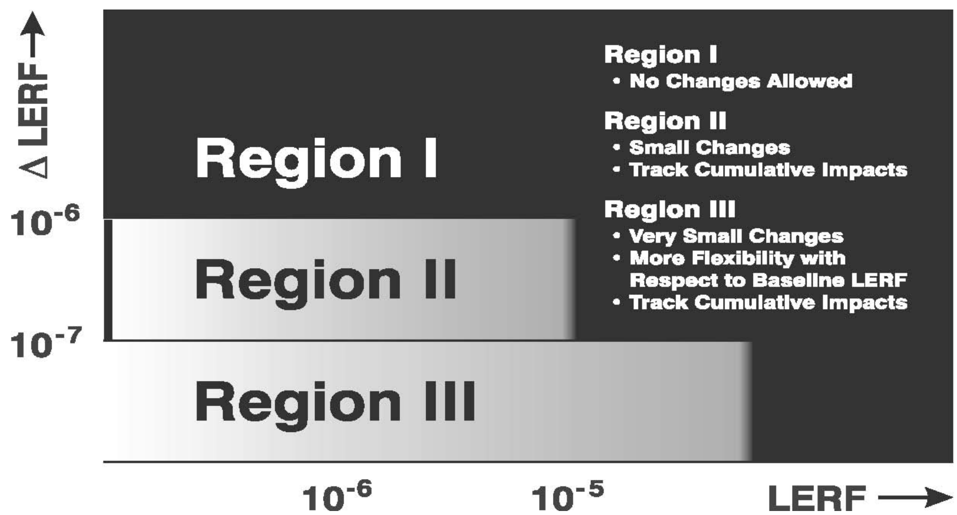

Figure 5 Acceptance guidelines* for large early release frequency

* 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 are not definitive; the numerical values associated with defining the regions in the figure are to be interpreted as indicative values only.

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

- If the application clearly shows 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 4 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 shows 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 5 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 as the calculated results move closer to the region boundaries.

The guidelines discussed above are applicable for at-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 2).

The technical review that relates to the risk evaluation will address the scope, level of detail, and technical adequacy of the analysis, including consideration of uncertainties as discussed in the next section. Section 2.6 of this guide discusses aspects covered by the management review, which include factors that are not amenable to PRA evaluation.

2.5 **Comparison of Probabilistic Risk Assessment Results with the Acceptance Guidelines**

This section provides guidance on comparing the results of the PRA with the acceptance guidelines described in Section 2.4 of this guide. 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 4 and 5 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 the region in which the application belongs 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 Part C of this regulatory guide, is being met. As discussed in Section 2.3.1 the scope of the PRA needed to support a particular application may include several hazard groups or plant operating modes. When it is necessary to combine the assessment of the risk implications from different hazard groups, it is important to develop an understanding of the relative level of realism associated with the modeling of each of the hazard groups. For example, the analysis of specific scope items, such as internal fire, internal flooding, or seismic initiating events, typically involves a successive screening approach that allows the detailed analysis to focus on the more significant contributions. The analysis of the less significant contributions is generally of a more conservative nature. In addition, for each of the risk contributors, there are unique sources of model uncertainty. The assumptions made in response to these sources of model uncertainty and any conservatism introduced by the analysis approach discussed above can bias the results. This is of particular concern for the assessment of importance measures with respect to the combined risk assessment and the relative contributions of the hazard groups to the various risk metrics.

Therefore, this comparison of the PRA results with the acceptance guidelines must be based on an understanding of the contributors to the PRA results and on the robustness of the assessment of those contributors 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. Section 2.5.4 of this guide provides guidance on what should be addressed. However, the types of uncertainty that impact PRA results and methods typically used for their analysis are briefly discussed first. More information can be found in NUREG-1855 (Ref. 12) and in some of the publications in the bibliography.

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 associated with events or phenomena being modeled that 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 associated with the analyst’s confidence in the predictions of the PRA model itself and 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. This section discusses the epistemic uncertainty; 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 epistemic 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 following sections summarize the treatment of PRA uncertainty. Detailed guidance is given in NUREG-1855 (Ref. 12). The bibliography may also be consulted for additional information.

2.5.2 *Parameter Uncertainty*

Each of the models that are 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 or her 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 Reference 15).

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 consensus models[7] 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 the 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

[7] NUREG-1855 (Ref. 12) defines a consensus model as one that has a publicly available published basis and has been peer reviewed and widely adopted by an appropriate stakeholder group. In addition, widely accepted PRA practices may be regarded as consensus models. Examples of the latter include the use of the constant probability of failure on demand model for standby components and the Poisson model for initiating events. For risk-informed regulatory decisions, the consensus model approach is one that NRC has utilized or accepted for the specific risk-informed application for which it is proposed.

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 loss-of-coolant accident (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 by 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.

2.5.4 *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 unavailable, but because they have not been refined to the level of the analysis of internal hazards.

Examples are the analysis of some external hazards 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. The next section includes approaches acceptable to the NRC staff for dealing with incompleteness.

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 ΔCDF and ΔLERF are very small, as defined by Region III in Figures 4 and 5, 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 ΔCDF and ΔLERF, 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 4 and 5, the closer the estimates of ΔCDF or ΔLERF are to their corresponding acceptance guidelines, the more detail will be required. Similarly, in Region II of Figures 4 and 5, the closer the estimates of ΔCDF or ΔLERF 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 (Section 2.4) 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. If it can be demonstrated that the state-of-knowledge correlation is unimportant, then a point estimate of the expected value can be used. This demonstration 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. For more detail, see Section 4 of NUREG-1855 (Ref. 12).

Consistent with the viewpoint that the guidelines are not to be used prescriptively, even if the calculated ΔCDF and ΔLERF 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[8] 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. It is not the intent that the search for alternatives should be exhaustive or 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 unacceptability (i.e., those associated with key sources of model uncertainty[9]) 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. (Section 7 of NUREG-1855 (Ref. 12) provides additional guidance on treating PRA uncertainty in the decisionmaking process.) 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. Reference 10 presents an approach 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 10 may be used to estimate LERF only in those cases when the plant is not close to the CDF and LERF benchmark values.

---

[8] In the ASME/ANS PRA standard (Ref. 14), a reasonable alternative assumption is one that has broad acceptance within the technical community and for which the technical basis for consideration is at least as sound as that of the assumption being made.

[9] In the ASME/ANS PRA standard (Ref. 14) a source of model uncertainty is labeled "key" when it could impact the PRA results that are being used in a decision, and consequently, may influence the decision being made.

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 should be supplemented by qualitative risk insights and traditional engineering analysis where appropriate. Qualitative risk insights include generic results that have been learned from previous PRAs 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 support the licensee's analysis and reduce the reliance of the staff review on the technical adequacy of the licensee PRA. However, as a general rule, applications that impact large numbers of SSCs will benefit from a PRA of sound technical adequacy.

Traditional engineering analysis provides insight into available margins and defense-in-depth. 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 2.1 and 2.2 of this guide 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. These results are one decisionmaking input 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.

The acceptability of the change supported by 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.

The NRC review of an application will consider all these factors. The review of PRA technical adequacy 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, therefore placing less emphasis on the technical adequacy 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 a 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 significance. 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-completion 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.

Section 2.4 of this guide indicates 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, approach the guidelines. Therefore, if the risk metrics approach the guidelines, the licensee's submittal should address the following issues:

- 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, respectively).

3. Element 3: Define Implementation and Monitoring Program

Careful consideration should be given to implementation of the proposed change and the associated performance-monitoring strategies. The primary goal of Element 3 is to ensure that no unexpected adverse safety degradation occurs due to the change(s) 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. Application-specific regulatory guides (Refs. 5, 7-9) discuss additional details of acceptable processes for implementation in specific applications.

Decisions concerning the implementation of LB changes should be made after considering 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 (e.g., data and models are adequate, engineering evaluations are verified and validated). A slower, phased approach to implementation (or other modes of partial implementation) would be expected when uncertainty in evaluation findings is higher and when 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 special treatment). In such situations, the potential introduction of common cause effects must be fully considered and included in the submittal.

The licensee should propose monitoring program(s) 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 the assumptions in the traditional engineering and probabilistic analyses conducted to justify the change. This may include monitoring associated with nonsafety-related SSCs if the analysis determines that those SSCs are 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.

Licensees will integrate, or at least coordinate, their monitoring for risk-informed changes with existing programs that monitor equipment performance and other operating experience on their site and industry-wide. In particular, monitoring that is performed in conformance with 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (the Maintenance Rule) 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 the Maintenance Rule does not include, or has a greater resolution of monitoring than the Maintenance Rule (component versus 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. 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), and
- 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 used to support 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 before 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 Reference 16).

Finally, in accordance with Criterion XVI of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, the monitoring program should identify any corrective actions to preclude the recurrence of unacceptable failures and/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.

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 under 10 CFR 50.54, "Conditions of Licenses" (e.g., quality assurance program changes under 10 CFR 50.54(a)). Licensees should (1) carefully review the proposed LB change 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, 10 CFR 50.91, "Notice for Public Comment; State Consultation," and 10 CFR 50.92, as well as the procedural requirements in 10 CFR 50.4, "Written Communications." Risk information that the licensee submits in support of the LB change request should meet the guidance in Section 6 of this regulatory guide.

Licensees may 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 information based on both traditional engineering analyses and 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 Reference 3), the NRC staff will request that the licensee 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 are likely to 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. Application-specific regulatory guides (Refs. 5, 7-9) present specific information on the staff's expectations in this regard.

5. Quality Assurance

As stated in Section 2 of this guide, the quality of the engineering analyses conducted should 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 PRA is to 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 6 of this guide.
- Use procedures that ensure that 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 are met.

6. Documentation

6.1 **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 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.

6.2 **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 its 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, Revision 2, "Quality Assurance Program Requirements (Operation)," issued February 1978 (Ref. 17).

6.3 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 licensee should submit the following information:

- 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 Part 20, "Standards for Protection against Radiation," and 10 CFR Part 100, "Reactor Site Criteria," if appropriate. (Relevant principles: LB changes meet the regulations, sufficient safety margins are maintained, and defense-in-depth philosophy is used).

- 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 is used).

- 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[10] 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,
- information to be provided as part of the plant's LB (e.g., FSAR, technical specifications, licensing condition), and
- whether provisions of Appendix B to 10 CFR Part 50 apply to the PRA.

The latter item 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 quality assurance program description.

An independent peer review is an important element of ensuring technical adequacy. The licensee's submittal should discuss measures used to ensure technical adequacy, such as a report of a peer review augmented by a discussion of the appropriateness of the PRA model for supporting a risk assessment of the LB change under consideration. The submittal should address any analysis limitations that are expected to impact the conclusion regarding acceptability of the proposed change.

---

10 In the ASME/ANS PRA standard (Ref. 14) an assumption is labeled "key" when it may influence (i.e., have the potential to change) the decision being made.

The licensee's resolution of the findings of the peer review should also be submitted. For example, this response could indicate whether the PRA was modified following the peer review or could justify why no change was necessary to support decisionmaking for the LB change under consideration. As discussed in Section 2.2 of this guide, the staff's decision on the proposed license amendment will be based on its independent judgment and review.

6.3.1 *Risk Assessment Methods*

To have confidence that the risk assessment 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 properly identified as proprietary in accordance with the regulations. 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.
- Documentation of the adequacy of the scope of the PRA.
- A description of the licensee's process to ensure PRA technical adequacy and a discussion as to why the PRA is of sufficient technical adequacy to support the current application.
- The key modeling assumptions[11] that are necessary to support the analysis or that impact the application.
- The event trees and fault trees that require modification to support analyses of the proposed change with a description of their modification.
- 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 following:

- The effects of the proposed change on the more significant sequences (e.g., sequences that contribute more than 5 percent to the risk) 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 the assessment of the full-scope, baseline 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 4.

- Information related to the assessment of the full-scope, baseline 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 5.

---

[11] In the ASME/ANS PRA standard, a modeling assumption is one that is related to a model uncertainty and is made with the knowledge that a different reasonable alternative assumption exists. A reasonable alternative assumption is one that has broad acceptance within the technical community and for which the technical basis for consideration is at least as sound as that of the assumption being made. An assumption is labeled "key" when it may influence (i.e., have the potential to change) the decision being made.

- Results of sensitivity 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.

6.3.2 *Cumulative Risks*

As part of evaluation of risk, licensees should understand the effects of the current 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.

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 which have not yet been incorporated into the baseline PRA model, and are therefore not reflected in the baseline risk. Documentation should include the following:

- 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 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.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees[12] may use this guide and information regarding the NRC's plans for using this regulatory guide. In addition, it describes how the NRC staff complies with the Backfit Rule (10 CFR 50.109) and any applicable finality provisions in 10 CFR Part 52.

Use by Applicants and Licensees

Applicants and licensees may voluntarily [13]use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the

---

12 In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

13 In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged**. <NOTE: If there is a current regulatory guide that is acceptable, then INSERT:** The acceptable guidance may be a previous version of this regulatory guide.>

Licensees may use the information in this regulatory guide for actions which do not require NRC review and approval such as changes to a facility design under 10 CFR 50.59 or 10 CFR Part 52 Appendices. Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, or promulgation of a rule requiring the use of this regulatory guide without further backfit consideration.

Additionally, an existing applicant may be required to adhere to new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409 and NRC Management Directive 8.4.

REFERENCES[1]

1. 60 FR 42622, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," *Federal Register,* Volume 60, Number 158, p. 42622, Washington, DC, August 16, 1995.

2. SECY-11-0151, "Annual Update of the Risk-Informed and Performance-Based Plan," U.S. Nuclear Regulatory Commission, October 27, 2011 (ML112620701).

3. NUREG-0800, Section 19.2, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," June 2007.

4. 51 FR 30028, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," *Federal Register*, Volume 51, p. 30028, Washington, DC, August 4, 1986.

5. Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," U.S. Nuclear Regulatory Commission, Washington, DC.

6. Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," U.S. Nuclear Regulatory Commission, Washington DC (withdrawn).

7. Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," U.S. Nuclear Regulatory Commission, Washington DC.

8. Regulatory Guide 1.178, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping," U.S. Nuclear Regulatory Commission, Washington, DC.

9. Regulatory Guide 1.201 (Trial Use), Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," U.S. Nuclear Regulatory Commission, Washington, DC.

10. W.T. Pratt et al., "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," NUREG/CR-6595, Revision 1, October 2004.

11. Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," U.S. Nuclear Regulatory Commission, Washington, DC.

12. NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making," Volume 1, March 2009.

---

[1] Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically through the NRC Librarythe NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR.Resource@nrc.gov.

13. Staff Requirements Memorandum to SECY-04-0118, "Plan for the Implementation of the Commission's Phased Approach to Probabilistic Risk Assessment Quality," U.S. Nuclear Regulatory Commission, Washington, DC, October 6, 2004.

14. ASME/ANS, "Addenda to ASME/ANS RA-S-2008 Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications," ASME/ANS RA-Sa-2009, American Society of Mechanical Engineers/American Nuclear Society, February 2009.[2]

15. G. Apostolakis and S. Kaplan, "Pitfalls in Risk Calculations," *Reliability Engineering,* Vol. 2, pp. 135–145, 1981.[3]

16. A. Mosleh et al., "Guidance on Modeling Common-Cause Failures in Probabilistic Risk Assessment," NUREG/CR-5485, November 1998.

17. Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," U.S. Nuclear Regulatory Commission, Washington, DC.

---

2 Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Three park Avenue, New York, New York 10016-5990; Telephone (800) 843-2763. Purchase information is available through the ASME web site store at http://www.asme.org/Codes/Publications/.

3 Copies of the non-NRC documents included in these references may be obtained directly from the publishing organization.

BIBLIOGRAPHY

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

Bohn, M.P., T.A. Wheeler, G.W. Parry, "Approaches to Uncertainty Analysis in Probabilistic Risk Assessment," NUREG/CR-4836, US Nuclear Regulatory Commission, January 1988.

Hickman, J.W., "PRA Procedures Guide," NUREG/CR-2300, US Nuclear Regulatory Commission, January 1983.

Kaplan, S., and B.J. Garrick, "On the Quantitative Definition of Risk," *Risk Analysis,* Vol. 1, pp. 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, MD, October 20-22, 1993), US Nuclear Regulatory Commission, NUREG/CP-0138, October 1994.

Parry, G.W., and P.W. Winter, "Characterization and Evaluation of Uncertainty in Probabilistic Risk Analysis," *Nuclear Safety,* 22(1), pp. 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 Safety (Special Issue on Treatment of Aleatory and Epistemic Uncertainty), Vol. 54, Nos. 2 and 3, November/December 1996.

APPENDIX A

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

A-1. 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 (see Figure 2 of Regulatory Guide 1.174) 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 (e.g., 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.

A-2. Technical Issues Associated With the Use of Importance Measures

In the implementation of the Maintenance Rule (Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants") and in industry guides for risk-informed applications (e.g., the "PSA Applications Guide"[1]), the Fussell-Vesely Importance, Risk Reduction Worth, and Risk Achievement Worth are the most commonly identified measures in the relative risk ranking of SSCs. However, in using 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

---

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

quantification techniques. These issues are discussed in detail below. In addition, the licensee should be aware of and adequately address two other issues: (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. 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 (CCFs)), the data used, or the success criteria chosen. The licensee should therefore make sure that the PRA is technically adequate.

In addition to the use of a technically adequate 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 below.

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 percent 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 ranging from 10^{-12} to 10^{-8} per reactor year (or possibly even lower for some ALWR designs). 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 hazards, external hazards, 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 takes 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 significant 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. A certain degree of subjectivity is 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 significant 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 ensure that the measures capture the impact of changes to the group in a logical way. The remainder of this paragraph provides an example of the issues that can arise. For front-line systems, one could 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 includes 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. For examples, in a two-division plant, 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, the appropriate determination must rely on a qualitative categorization by the licensee, as part of the integrated decisionmaking process.

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 or 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 relate 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 account for the risk increase resulting from 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 ensure that these SSCs are considered.