POLICY ISSUE
(Information)

April 24, 2002 SECY-02-0070

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PUBLICATION OF REVISIONS 1 TO REGULATORY GUIDE 1.174 AND SRP CHAPTER 19 AND NOTICE OF A STAFF PLAN FOR ENDORSING CONSENSUS PROBABILISTIC RISK ASSESSMENT STANDARDS AND INDUSTRY PEER REVIEW PROGRAMS

PURPOSE:

(1) To inform the Commission of the staff's intention to publish Revisions 1 to Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" and Standard Review Plan Chapter 19, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance."

(2) To provide, for the Commission's information, the staff's plan for endorsement of pending ASME and ANS consensus standards and industry peer review programs on probabilistic risk assessment (PRA) in a new regulatory guide and standard review plan chapter.

BACKGROUND:

The Commission's May 20, 1998, Staff Requirements Memorandum (SRM) approved the publication of Regulatory Guide (RG) 1.174 and Standard Review Plan (SRP) Chapter 19 which

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discuss the scope, level of detail and quality of licensee PRA submittals in support of risk-informed changes to the licensing basis. It also directed that an annual review be performed to insure that new experience in PRA practice is regularly incorporated.

The Commission's April 18, 2000, SRM directed the staff to "provide its recommendations to the Commission for addressing the issue of PRA quality until the ASME and ANS standards have been completed, including the potential role of an industry PRA certification process."

In SECY-00-0162, dated July 28, 2000, the staff approach was described which included identification of the scope and "minimal functional attributes necessary to ensure the PRA" is capable of providing certain results, such as core damage frequency, large early release frequency (LERF) and accident contributors. It further noted that "if appropriate, the staff will endorse them [e.g., ASME PRA standard] in an update of Regulatory Guide 1.174 or elsewhere to support other risk-informed activities.......The staff endorsement may take exception to or include additional specific criteria to address any identified weaknesses in the standards to ensure that PRAs used in regulatory decision-making will have an adequate technical basis." The staff also indicated that "to strengthen this guidance [RG 1.174 and SRP 19] and thus improve the efficiency and consistency of the staff review process, the staff intends to include the information [Attachments 1 and 2] from the SECY paper in the next update of the guide and SRP chapter." Attachment 1 provided details on functional attributes of PRAs and Attachment 2 provided examples of risk-informed decisionmaking.

The Commission's October 27, 2000, SRM indicated that it had no objection to the proposed update of RG 1.174 and SRP Chapter 19, that "the timely resolution of PRA quality requirements is necessary to support existing and developing risk-informed regulation," and that the staff should expand discussion (in Attachment 2 to SECY-00-0162) to include further examples "of how PRA quality influences risk-informed decision-making."

DISCUSSION:

RG 1.174 (as DG-1110) and SRP Chapter 19 were revised and issued in June 2001 for public review and comment. Proposed changes to the RG and SRP Chapter were made in four areas:

- The staff has postulated that issues may arise in relation to a licensing basis change request which cause plant risk to increase, perhaps substantially and beyond an acceptable level. In response to such an eventuality, NRC would be required to exercise its statutory authority to request additional information from licensees and require them to take action. The proposed regulatory guide revision states that risk-related information may be requested by the staff if new, unforeseen hazards or substantially greater prospects for a known hazard emerge as a result of a licensee change request, even if the licensee did not originally submit risk information in the request.[1]

[1]This staff guidance was the subject of SECY-99-246, dated October 12, 1999. Commission approval was provided in an SRM dated January 5, 2000.

- The staff became aware that underlying assumptions which form a basis for the current LERF guidelines and which include assumptions of nuclear plant fuel, power levels and fuel burnup rates in effect over the past few years, may be affected by increases in these parameters. As a result, the staff proposed the following advice to licensees indicating to them that the staff may need to reexamine the appropriateness of current LERF guidelines:
  - Proposed reactor power level increases above 3800 Mwt may need to be evaluated for their impact on LERF.
  - Increases in fuel burnup beyond 40,000 MWD/MT are not expected to have an significant effect on current LERF guidelines, but a staff sponsored expert panel is investigating the effects on source terms arising from these higher burnup rates and the use of mixed-oxide fuel. The implications for LERF will then be assessed.

- As a result of the October 27, 2000, SRM, the staff was directed to provide the nuclear industry with guidance on the development of a PRA acceptable for risk-informed applications. This guidance, contained in SECY-00-0162, Attachment 1, dated July 28, 2000, included the identification and description of the scope and the minimum functional and technical attributes of a PRA. This input was included primarily in Attachment 1 to the proposed regulatory guide revision.

- Also as a result of the same SRM, the staff was directed to provide examples of applications which used risk insights in the decision-making process, as referred to in SECY-00-0162, Attachment 2.

Comments, as indicated below, were received from stakeholders including the Nuclear Energy Institute, nuclear steam supply system owners groups, individual utilities and unaffiliated members of the public (Reference 1):

- Risk-information for unforeseen hazards or greater prospect for known hazards–
  - No public comments received.

- Increases in power level, fuel burnup and use of mixed-oxide fuel–
  - Several stakeholders suggested that more justification was needed if this new staff guidance was to be adopted. In addition, it was pointed out that nuclear plants had already made application for power levels above 3800 MWt and so the precedent had already been set for these power levels without the as-yet-to-be-developed requirements alluded to in DG-1110. Their concern was that additional guidance was needed immediately if new requirements were to be initiated in the near term.

- Description of the scope and minimum functional/technical PRA attributes–
  - Several stakeholders felt that the revised RG departed extensively from the original intent of RG 1.174 in that it would now be overly prescriptive and would not allow any room for licensee interpretation and judgement in the construction of their PRAs.
  - Several stakeholders felt that new requirements regarding Level 2, late containment failure, were being added. They noted that RG 1.174 only considered LERF and they interpreted NUREG-1150 as demonstrating that late

containment failures did not contribute to risk, so they objected to the discussion which elaborated on Level 2 technical attributes.[2]
- – Several stakeholders felt that the RG did not appear to be the appropriate place to include the SECY-00-0162 guidance.

- Examples of applications using risk-insights in the decision-making process–
  - – No comments were received on the risk-informed in-service inspection example provided.

After reviewing the public comments the staff has revised RG 1.174 and SRP Chapter 19 (Attachments 1 and 2) as follows:

- Risk-information for unforeseen hazards or greater prospect for known hazards–
  - – Keep the updated revision in the RG and SRP

- Increases in power level, fuel burnup and use of mixed-oxide fuel–
  - – Remove this revision from the RG and SRP until the staff expert panel investigation is complete and a staff position is formulated.

- Description of the scope and minimum functional/technical PRA attributes–
  - – Rather than include this guidance as part of RG 1.174, the staff intends to develop a new RG and SRP chapter. The new RG and SRP chapter will provide guidance to licensees on how to use the PRA standards and industry peer review programs to demonstrate that the risk input to a risk-informed decision is technically defensible. This new RG and SRP chapter will be used to support a broader set of regulatory issues, including license amendments (the subject of RG 1.174) and other activities such as the proposed 10CRF50.69. In addition, it will serve as the vehicle for staff endorsement of all future industry PRA standards and peer review programs. Attachment 3 contains the staff plan for development of this RG and SRP chapter. It will be incorporated into the Risk Informed Regulation Implementation Plan. Consequently, Appendix A in DG-1110 and references to it in the SRP will be removed from the final versions.

- Examples of applications using risk-insights in the decision-making process–
  - – The staff will modify and expand the risk-insights examples in SECY-00-162, Attachment 2, and relocate them to the new RG and SRP chapter discussed above. This location appears the most appropriate because the new RG and SRP chapter will support all risk-informed activities that address PRA quality, including those discussed in RG 1.174.

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[2]In a subsequent public meeting the staff clarified that, in NUREG 1150, late containment failure was a significant contributor, on the order of approximately 30 percent to latent cancer risk.

Stakeholder Communications:

The staff held public meetings in December 2001 and February 2002 to present the staff's intentions with regard to these initiatives. Generally positive feedback was received on the staff plans to endorse the PRA standard and industry peer review program in a new RG and associated SRP. The new proposed RG and SRP chapter will be issued for public comment.

COORDINATION:

The proposed revisions to RG 1.174 and SRP Chapter 19 were reviewed by ACRS in a meeting on February 7, 2002. All substantive changes to be included in the updated RG and SRP have been the subject of previous ACRS reviews and agreement. However, the ACRS raised issues in a recent letter (to EDO, March 19, 2002) regarding the proposed rulemaking and associated guidance for risk-informing the special treatment requirements of 10CFR Part 50. The ACRS noted that late containment failure and inadvertent release of radioactive material should be considered in the risk metrics that supplement core damage frequency and large early release frequency. Once a staff position on this issue is established, it will be incorporated, as appropriate, in the new proposed RG and associated SRP or in a future update of RG 1.174 and SRP Chapter 19.

The Office of the General Counsel has also reviewed both documents and has no legal objection to their publication.

CONCLUSION:

The staff plans to publish Revisions 1 of RG 1.174 and SRP Chapter 19, provided in Attachments 1 and 2.

The staff also requests that the Commission make note of the staff's plan to develop a new RG and SRP chapter that would provide guidance to licensees and the staff, respectively, on how to use standards and other industry programs in evaluating the technical appropriateness of PRA results for risk-informed applications (provided in Attachment 3). The staff plans to continue meeting with the ACRS as this new RG and SRP chapter are developed.

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Attachments: 1. Regulatory Guide 1.174 (Revision 1)
2. SRP Chapter 19 (Revision 1)
3. Staff plan for endorsing industry standard and peer review programs

Reference: 1. Memorandum from Mary Drouin, RES, to Mark Cunningham, RES, "Public Comments on DG-1110 (Revision 1 to RG 1.174) and Revision 1 to SRP Chapter 19," March 20-02.

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

April 2002

REGULATORY GUIDE

~~(Draft was issued as DG-1110)~~

REGULATORY GUIDE 1.174
Revision 1

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

1. PURPOSE AND SCOPE

1.1 INTRODUCTION

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

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

[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 complete staff review or approval and does not represent an official NRC 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 and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments may be submitted electronically or downloaded through the NRC's interactive web site at <WWW.NRC.GOV> through Rulemaking. Copies of comments received may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by~~

~~**September 17, 2001.**~~

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Licensee-initiated LB changes that are consistent with currently approved staff positions (e.g., regulatory guides, standard review plans, branch technical positions, or the Standard Technical Specifications) are normally evaluated by the staff using traditional engineering analyses. A licensee generally would not be expected to submit risk information in support of the proposed change.

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

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

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

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

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

1.2 BACKGROUND

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

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

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

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

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

~~To facilitate the use of PRA, the Commission also directed the staff, in response to SECY-00-0162, "Addressing PRA Quality in Risk-Informed Activities" (Ref. 4), to define acceptable PRA quality. See Appendix A to this guide for details on PRA characteristics and attributes.~~

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

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

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

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

This regulatory guide also makes use of the NRC's Safety Goal Policy Statement (Ref. 5). As discussed below, one key principle in risk-informed regulation is that proposed increases in CDF and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. The safety goals (and associated quantitative health objectives (QHOs)) define an acceptable level of risk that is a small fraction (0.1%) of other risks to which the public is exposed. The acceptance guidelines defined in this regulatory guide (in Section 2.2.4) are based on subsidiary objectives derived from the safety goals and their QHOs.

1.3 PURPOSE OF THIS REGULATORY GUIDE

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

1.4 SCOPE OF THIS REGULATORY GUIDE

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

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

Consideration of the Commission's Safety Goal Policy Statement (Ref. 5) is an important element in regulatory decisionmaking. Consequently, this regulatory guide provides acceptance guidelines consistent with this policy statement.

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

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

1.5 RELATIONSHIP TO OTHER GUIDANCE DOCUMENTS

Directly relevant to this regulatory guide is the Standard Review Plan (SRP) designed to guide the NRC staff evaluations of licensee requests for changes to the LB that apply risk insights (Ref. 3), as well as guidance that is being developed in selected application-specific regulatory guides and the corresponding standard review plan chapters. Related regulatory guides have been developed on inservice testing, inservice inspection, graded quality assurance, and technical specifications (Refs. 6-9). 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. The staff recognizes that the risk analyses necessary to support regulatory decisionmaking may vary with the relative weight that is given to the risk assessment element of the decisionmaking process. The burden is on the licensee who requests a change to the LB to justify that the chosen risk assessment approach, methods, and data are appropriate for the decision to be made.

The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

2. AN ACCEPTABLE APPROACH TO RISK-INFORMED DECISIONMAKING

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

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

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

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

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

3. The proposed change maintains sufficient safety margins.

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

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

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

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

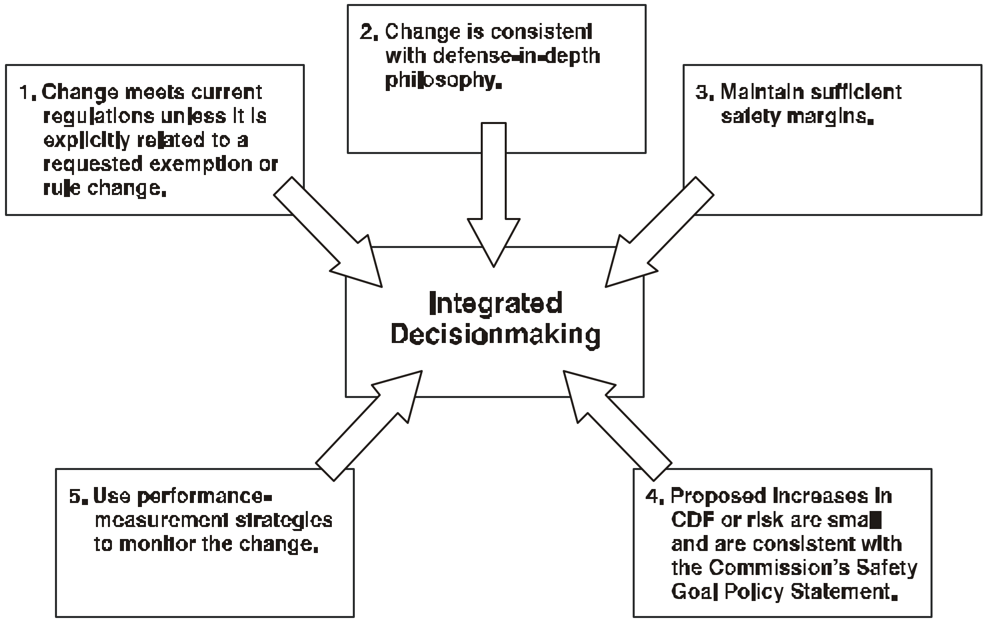

Figure 1. Principles of Risk-Informed Integrated Decisionmaking

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

! All safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly by identifying and taking advantage of opportunities to reduce risk, and not just to eliminate requirements the licensee sees as undesirable. For those cases when risk increases are proposed, the benefits should be described and should be commensurate with the proposed risk increases. The approach used to identify changes in requirements should be used to identify areas where requirements should be increased~~[3]~~ as well as where they can be reduced.

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

! ~~The portions of the plant-specific PRA relevant to the application should contain the characteristics and attributes of a PRA as defined in Appendix A. It should also be subjected to an independent peer review to determine whether it contains these characteristics and attributes.[4]~~

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[3] ~~The NRC staff is aware of but does not endorse guidelines that have been developed (e.g., by the Nuclear Energy Institute) to assist in identifying potentially beneficial changes to requirements.~~

[4] ~~As discussed in Section 2.2.3.3 below, such a peer review is not a replacement for NRC review. Such a process has been developed; it is the Nuclear Energy Institute (NEI) 00-02, "PRA Peer Review Process Guidance" (Ref. 11). This process has not been endorsed by the NRC staff at this time.~~

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

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

- The use of core damage frequency (CDF) and large early release frequency (LERF)[5] as bases for PRA acceptance guidelines is an acceptable approach to addressing Principle 4. Use of the Commission's Safety Goal QHOs in lieu of LERF is acceptable in principle, and licensees may propose their use. However, in practice, implementing such an approach would require an extension to a Level 3 PRA, in which case the methods and assumptions used in the Level 3 analysis, and associated uncertainties, would require additional attention.

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

- The acceptability of proposed changes should be evaluated by the licensee in an integrated fashion that ensures that all principles are met.[6]

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

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

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

[6] ~~One important element of integrated decisionmaking can be the use of an "integrated decisionmaking panel." Such a panel is not a necessary component of risk-informed decisionmaking; but when it is used, the key principles and associated decision criteria presented in this regulatory guide still apply and must be shown to have been met or to be irrelevant to the issue at hand.~~

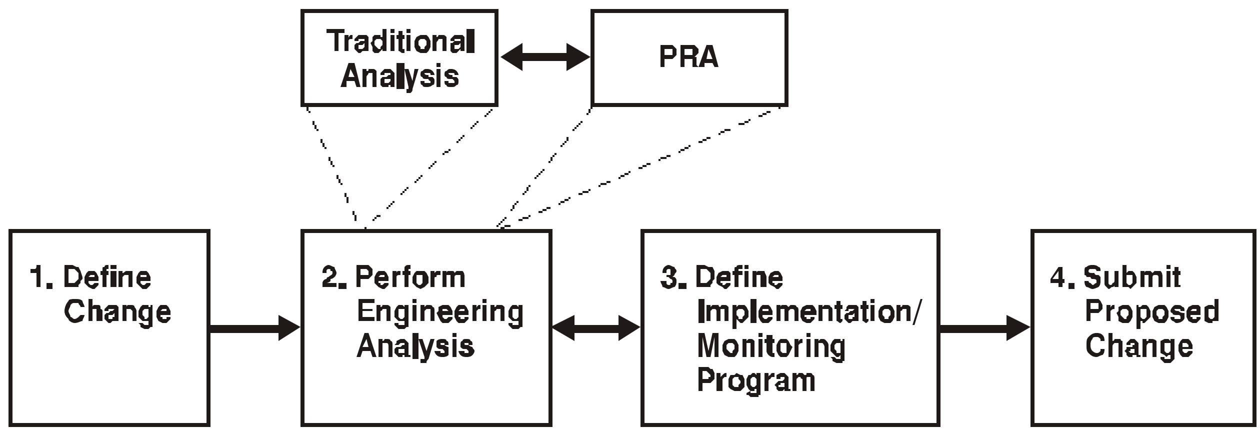


Figure 2. Principal Elements of Risk-Informed, Plant-Specific Decisionmaking

2.1 ELEMENT 1: DEFINE THE PROPOSED CHANGE

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

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

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

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

2.1.1 Combined Change Requests

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

1. CCRs in which any individual change increases risk;

2. CCRs in which each individual change decreases risk.

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

2.1.2 Guidelines for Developing CCRs

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

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

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

2.2 ELEMENT 2: PERFORM ENGINEERING ANALYSIS

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

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

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

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

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

2.2.1.1 Defense in Depth. The engineering evaluation should evaluate whether the impact of the proposed LB change (individually and cumulatively) is consistent with the defense-in-depth philosophy. In this regard, the intent of the principle is to ensure that the philosophy of defense in depth is maintained, not to prevent changes in the way defense in depth is achieved. The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance. If a comprehensive risk analysis is done, it can be used to help determine the appropriate extent of defense in depth (e.g., balance among core damage prevention, containment failure, and consequence mitigation) to ensure protection of public health and safety. When a comprehensive risk analysis is not or cannot be done, traditional defense-in-depth considerations should be used or maintained to account for uncertainties. The evaluation should consider the intent of the general design criteria, national standards, and engineering principles such as the single failure criterion. Further, the evaluation should consider the impact of the proposed LB change on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes. As stated earlier, the licensee should select the engineering analysis techniques, whether quantitative or qualitative, traditional or probabilistic, appropriate to the proposed LB change.

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

Consistency with the defense-in-depth philosophy is maintained if:

- A reasonable balance is preserved among prevention of core damage, prevention of containment failure, and consequence mitigation.

- Over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided.

- System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).

- Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed.

- Independence of barriers is not degraded.

- Defenses against human errors are preserved.

- The intent of the General Design Criteria in Appendix A to 10 CFR Part 50 is maintained.

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

- Codes and standards or their alternatives approved for use by the NRC are met.

- Safety analysis acceptance criteria in the LB (e.g., FSAR, supporting analyses) are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

Application-specific guidelines reflecting this general guidance have been developed and may be found in the application-specific regulatory guides (Refs. 6-9).

2.2.2 Evaluation of Risk Impact, Including Treatment of Uncertainties

The licensee's risk assessment may be used to address the principle that proposed increases in CDF and risk are small and are consistent with the intent of the NRC's Safety Goal Policy Statement (Ref. 5). For purposes of implementation, the licensee should assess the expected change in CDF and LERF. The necessary sophistication of the evaluation, including the scope of the PRA (e.g., internal events only, full power only), depends on the contribution the risk assessment makes to the integrated decisionmaking, which depends to some extent on the magnitude of the potential risk impact. For LB changes that may have a more substantial impact, an in-depth and comprehensive PRA analysis, one appropriate to derive a quantified estimate of the total impact of the proposed LB change, will be necessary to provide adequate justification. In other applications, calculated risk-importance measures or bounding estimates will be adequate. In still others, a qualitative assessment of the impact of the LB change on the plant's risk may be sufficient.

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

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

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

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

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

2.2.3 Quality of PRA Analysis

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

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

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

2.2.3.1 Scope. ~~For PRAs used in risk-informed activities, the following scope and level of risk characterization, as summarized in Table 1, are considered.~~

~~Plant operating states (POSs) are used to subdivide the plant operating cycle into unique states such that the plant response can be assumed to be the same for all subsequent accident initiating events. Operational characteristics (such as reactor power level; in-vessel temperature, pressure, and coolant level; equipment operability; and changes in decay heat load or plant conditions that allow new success criteria) are examined to identify those important to defining plant operational states. The important characteristics are used to define the states and the fraction of time spent in each state is estimated using plant specific information. The risk perspective is based on the total risk connected with the operation of the reactor, which includes not only full power operation, but low power and shutdown conditions. Therefore, to gain the maximum benefit from a PRA, the model addresses all modes of operation.~~

~~Table 1 List of Items Defining PRA Scope and Risk Characterization~~

~~Item~~		~~Desired Scope and Level of Risk Characterization~~
~~POS~~		~~full and low power, hot and cold shutdown~~
~~Initiating Events~~	~~internal~~	~~• transients • LOCAs • floods • fires~~
	~~external~~	~~• seismic events • high wind • others~~
~~Risk Characterization~~		~~Level 1: core damage frequency~~
		~~Level 2: large early release frequency and long-term containment integrity~~
		~~Level 3: not required~~

~~Initiating events are the events that have the ability to challenge the condition of the plant. These events include failure of equipment from either "internal plant causes" such as hardware faults, operator actions, floods or fires, or "external plant causes" such as earthquakes or high winds. The risk perspective is based on the total risk connected with the operation of the reactor, which includes events from both internal and external sources. Therefore, to gain the maximum benefit from a PRA, the model should address both internal and external initiating events.~~

~~The metrics used for risk characterization in risk-informed applications are CDF and LERF (as a surrogate for early fatalities). Issues related to the reliability of barriers, in particular containment integrity and consequence mitigation, are addressed through consideration of defense in depth. To provide the risk perspective for use in decisionmaking, a Level 1 PRA is required. A limited Level 2 PRA is needed to address LERF and may be helpful in addressing issues related to long-term containment integrity. A Level 3 PRA is not required.~~

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

~~Table 2 provides a list of general technical elements required to provide acceptable results for a PRA. A PRA that is missing one or more of these elements would not be considered a complete PRA.~~

~~Table 2 Technical Elements of an Acceptable PRA~~

~~Scope/Level of Analysis~~	~~Technical Element~~	
	~~Applicable to all Internal & External Events~~	
~~Level 1~~	• ~~Initiating event analysis~~ • ~~Success criteria analysis~~ • ~~Accident sequence analysis~~ • ~~Systems analysis~~ • ~~Internal flood analysis~~ • ~~Internal fire analysis~~ • ~~External hazards analysis~~	• ~~Parameter estimation analysis~~ • ~~Human reliability analysis~~ • ~~Quantification~~ • ~~Interpretation of results~~
~~Level 2~~	• ~~Plant damage state analysis~~ • ~~Accident progression analysis~~	• ~~Quantification~~ • ~~Interpretation of results~~

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

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

If the impacts of a change to the plant cannot be associated with elements of the PRA, the PRA should be modified accordingly or the impact of the change should be evaluated qualitatively as part of the integrated decisionmaking ~~panel~~ process, as discussed in ~~Appendix A~~ Section

2.2.6. In any case, the effects of the changes on the reliability and unavailability of systems, structures, and components or on operator actions should be appropriately accounted for.

2.2.3.3 PRA Technical Acceptability. In the current context, technical acceptability will be ~~defined~~ understood as being determined by ~~measuring~~ the adequacy of the actual modeling and the reasonableness of the assumptions and approximations. A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices, commensurate with the scope, and level of detail, ~~and technical acceptability~~ required as discussed above. ~~Appendix A provides a summary of the characteristics and attributes of a PRA acceptable to the staff.~~ Several different approaches may be used to assess the technical acceptability of a PRA. ~~Regardless of the approach chosen, they all must assess technical acceptability against characteristics and attributes as described in Appendix A.~~ One approach a licensee could use to assess ~~this~~ technical acceptability is to perform a peer review of the PRA. ~~In this case, the submittal should document the review process described in Appendix A.~~ The documentation should include the qualification of the reviewers, the summarized review findings, and resolutions to these findings where applicable. Industry PRA certification programs and PRA cross-comparison studies could also be used to help assess appropriate scope, level of detail, and technical acceptability of the PRA. If such programs or studies are to be used, a description of the program, including the approach and standard or guidelines to which the PRA is compared, the depth of the review, and the make-up and qualifications of the personnel involved should be provided for NRC review. Based on the peer review or certification process and on the findings from this process, the licensee should justify why the PRA is adequate for the present application in terms of scope, level of detail, and technical acceptability. A staff review cannot be replaced in its entirety by a peer review, a certification, or cross-comparison, although the more confidence the staff has in the review that has been performed for the licensee, the less rigor should be expected in the staff review.[7] (delete footnote)

The staff is currently developing a regulatory guide to endorse the ASME PRA standard. This new guide will provide guidance on how the PRA standard may be used to better understand the level of confidence in the PRA results and their role in decision-making. Also forming a part of the guide will be the staff endorsement of PRA standards or industry programs, including exceptions or additional staff requirements.

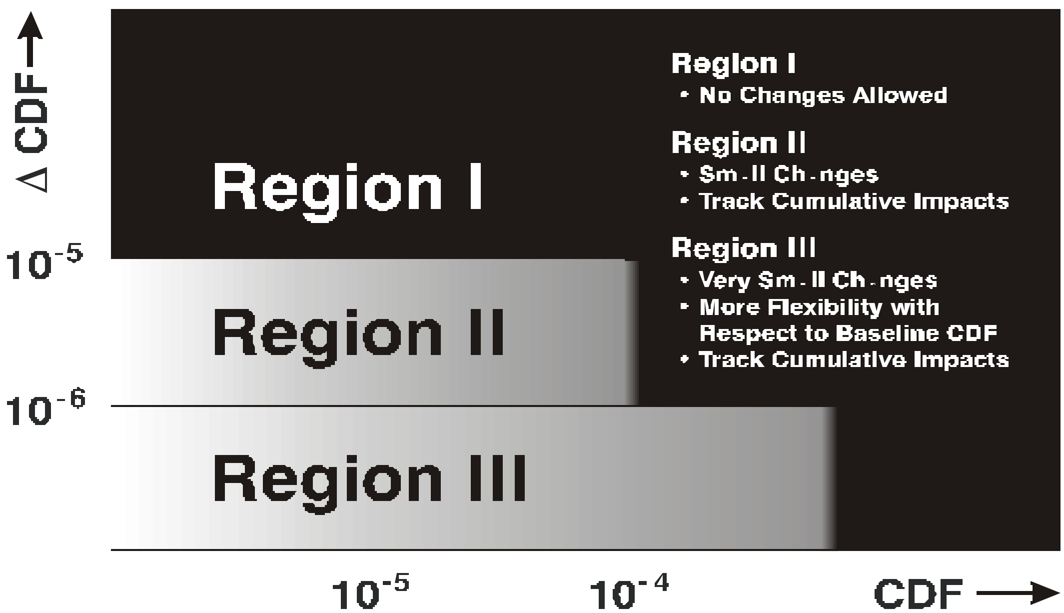
~~The NRC has not developed its own formal standards nor has it yet endorsed an industry standard for PRAs submitted in support of applications for changes to a plant's LB that are covered by this regulatory guide. However, the~~ NRC continues to support ongoing initiatives to develop ~~such~~ industry PRA standards and expects that ~~ultimately~~ PRA standards will be ~~developed and~~ endorsed by the NRC that are suitable for regulatory decisionmaking as described in this regulatory guide. Standards either completed or c~~C~~urrently under development cover ~~are standards for~~ internal events, external events (e.g., seismic events), low power and shutdown

[7] ~~In April 2000, the Nuclear Energy Institute (NEI) submitted a process (Ref. 11) for a peer review of licensee PRAs for use in categorizing SSCs with respect to special treatment requirements (i.e., supporting NRC's risk-informed "Option 2" work (SECY-99-256, Ref. 12)). This peer review process may also be of use in LB changes (as well as other regulatory activities not addressed here) since NEI now considers the process applicable to all risk-informed licensee submittals. ; if so, future revisions of this guide may endorse this certification process.~~

conditions.[8] In the interim, the NRC staff is continuing to evaluate PRAs submitted in support of specific applications using the guidelines given in Sections 2.2.3 ~~(including Appendix A)~~ and Section 2.5 of this regulatory guide, ~~and~~ Chapter 19 of the Standard Review Plan (Ref. 3), and the information contained in SECY-00-0162 (Ref. 4) which defines minimum technical attributes for a technically acceptable PRA. ~~and is folding the experience gained from these reviews back into the standards development process~~. In addition, the references and bibliography provide information that licensees may find useful in deciding on the acceptability of their PRA.

2.2.4 Acceptance Guidelines

The risk-acceptance guidelines presented in this regulatory guide are based on the principles and expectations for risk-informed regulation discussed in Section 2, and they are structured as follows. Regions are established in the two planes generated by a measure of the baseline risk metric (CDF or LERF) along the x-axis, and the change in those metrics (△CDF or △LERF) along the y-axis (Figures 3 and 4) and acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full-scope (including internal events, external events, full power, low power, and shutdown) assessment of the change in risk metric, and when necessary, as discussed below, the baseline value of the risk metric (CDF or LERF). However, it is recognized that many PRAs are not full scope and PRA information of less than full scope may be acceptable as discussed in Section 2.2.5 of this regulatory guide.



[8] The American Society of Mechanical Engineers (ASME) is developing a draft standard, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications"; it will be for Level 1 and Level 2 (LERF only) PRAs for internal events (excluding fire) that occur during full-power operations.

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

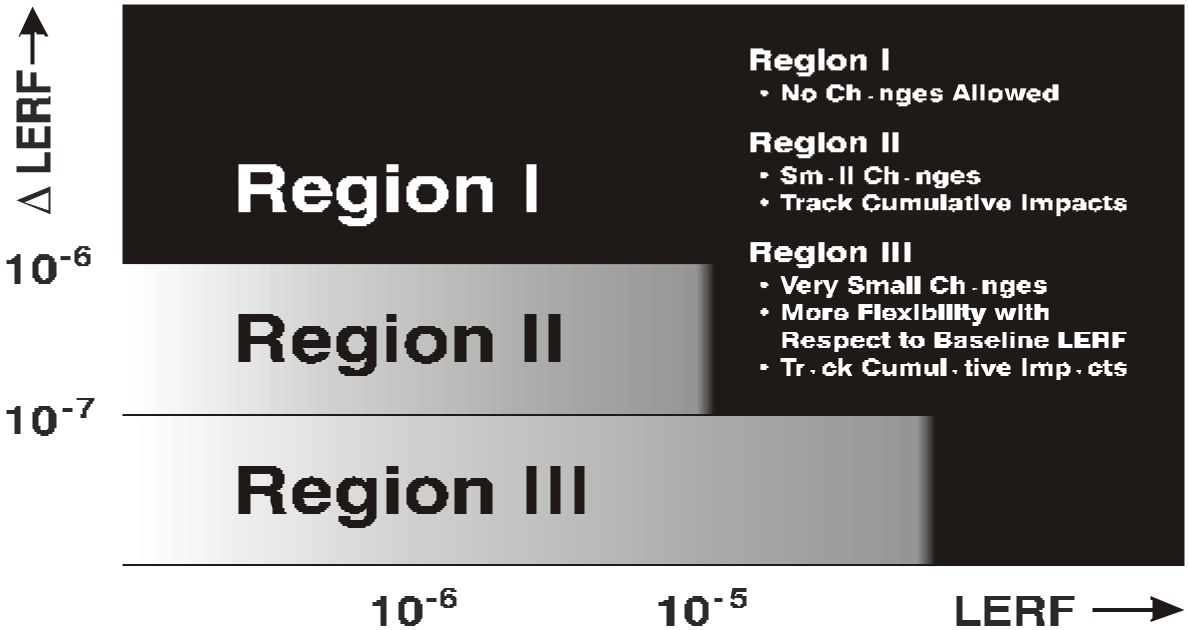


Figure 3. Acceptance Guidelines* for Core Damage Frequency (CDF)

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

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

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

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

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

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

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

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

AND

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

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

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

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

These guidelines are intended to provide assurance that proposed increases in CDF and LERF are small and are consistent with the intent of the Commission's Safety Goal Policy Statement (Ref. 5).

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

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

~~The risk analyses from which the current LERF guidelines were derived are based on~~ $\cancel{UO_2}$ ~~fueled cores at power levels up to 3800 Mwt and fuel burnups of approximately 40,000 MWD/MT. Small increases in power level to a resultant power level, no more than 3800Mwt, are not expected to have any appreciable effect on the current LERF guideline. However, power level increases resulting in levels above 3800 Mwt may need to be evaluated for their impact on these LERF guidelines.~~

~~Changes in fuel burnup are also not expected to have any appreciable effect on the current LERF guideline because early fatality risks are dominated by the short-lived fission products, while high burnup primarily affects the long-lived fission products. To address these issues, the NRC is convening a group of experts to identify and to rank in importance the phenomena related to high burnup and mixed oxide (MOX) source terms. The experts' report is expected to be published for public comment. The NRC staff will use the results of this expert elicitation to establish the basis for any changes to the current LERF guidelines that may be proposed.~~

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

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

2.2.5 Comparison of PRA Results with the Acceptance Guidelines

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

The intent of comparing the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4, discussed in Section 2, is being met. This decision must be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not. This is a somewhat subjective process, and the reasoning behind the decisions must be well documented. Guidance on what should be addressed follows in Section 2.2.5.4; but first, the types of uncertainty that impact PRA results and methods typically used for their analysis are briefly discussed. More information can be found in some of the publications in the Bibliography.

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

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

2.2.5.2 Parameter Uncertainty. Each of the models that is used, either to develop the PRA logic structure or to represent the basic events of that structure, has one or more parameters. Typically, each of these models (e.g., the Poisson model for initiating events) is assumed to be appropriate. However, the parameter values for these models are often not known perfectly. Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. They are typically characterized by establishing probability distributions on the parameter values. These distributions can be interpreted as expressing the analyst's degree of belief in the values these parameters could take, based on his state of knowledge and conditional on the underlying model being correct. It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results (e.g., CDF, accident sequence frequencies, LERF) of the PRA. However, the analysis must be done to correlate the sample values for different PRA elements from a group to which the same parameter value applies (the so-called state-of-knowledge dependency; see Ref. 13).

2.2.5.3 Model Uncertainty. The development of the PRA model is supported by the use of models for specific events or phenomena. In many cases, the industry's state of knowledge is incomplete, and there may be different opinions on how the models should be formulated. Examples include approaches to modeling human performance, common cause failures, and reactor coolant pump seal behavior upon loss of seal cooling. This gives rise to model uncertainty. In many cases, the appropriateness of the models adopted is not questioned and these models have become, de facto, the standard models to use.

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

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

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

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

2.2.5.4 Completeness Uncertainty. Completeness is not in itself an uncertainty, but a reflection of scope limitations. The result is, however, an uncertainty about where the true risk lies. The problem with completeness uncertainty is that, because it reflects an unanalyzed contribution, it is difficult (if not impossible) to estimate its magnitude. Some contributions are unanalyzed not because methods are not available, but because they have not been refined to the level of the analysis of internal events. Examples are the analysis of some external events and the low power and shutdown modes of operation. There are issues, however, for which methods of analysis have not been developed, and they have to be accepted as potential limitations of the technology. Thus, for example, the impact on actual plant risk from unanalyzed issues such as the influences of organizational performance cannot now be explicitly assessed.

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

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

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

For larger values of 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 3 and 4, 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 3 and 4, 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 were developed, the appropriate numerical measures to use in the initial comparison of the PRA results to the acceptance guidelines are mean values. The mean values referred to are the means of the probability distributions that result from the propagation of the uncertainties on the input parameters and those model uncertainties explicitly represented in the model. While a formal propagation of the uncertainty is the best way to correctly account for state-of-knowledge uncertainties that arise from the use of the same parameter values for several basic event probability models, under certain circumstances, a formal propagation of uncertainty may not be required if it can be demonstrated that the state-of-knowledge correlation is unimportant. This will involve, for example, a demonstration that the bulk of the contributing scenarios (cutsets or accident sequences) do not involve multiple events that rely on the same parameter for their quantification.

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

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

When the PRA is not full scope, it is necessary for the licensee to address the significance of the out-of-scope items. The importance of assessing the contribution of the out-of-scope portions of the PRA to the base case estimates of CDF and LERF is related to the margin between the as-calculated values and the acceptance guidelines. When the contributions from the modeled contributors are close to the guidelines, the argument that the contribution from the missing items is not significant must be convincing, and in some cases may require additional PRA analyses. When the margin is significant, a qualitative argument may be sufficient. The contribution of the out-of-scope portions of the model to the change in metric may be addressed by bounding analyses, detailed analyses, or by a demonstration that the change has no impact on the unmodeled contributors to risk. In addition, it should also be demonstrated that changes based on a partial PRA do not disproportionally change the risk associated with those accident sequences that arise from the modes of operation not included in the PRA.

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

If only a Level 1 PRA is available, in general, only the CDF is calculated and not the LERF. An approach is presented in Reference 10 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.

2.2.6 Integrated Decisionmaking

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

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

Traditional engineering analysis provides insight into available margins and defense in depth. In the example of the operational assessment of steam generator tubes discussed later in this section, it is traditional engineering analysis that provides assurance that structural integrity and leakage criteria have been satisfied. With few exceptions, these assessments are performed without any quantification of risk.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.3 ELEMENT 3: DEFINE IMPLEMENTATION AND MONITORING PROGRAM

Careful consideration should be given to implementation and performance-monitoring strategies. The primary goal for this element is to ensure that no adverse safety degradation occurs because of the changes to the LB. The staff's principal concern is the possibility that the aggregate impact of changes that affect a large class of SSCs could lead to an unacceptable increase in the number of failures from unanticipated degradation, including possible increases in common cause mechanisms. Therefore, an implementation and monitoring plan should be developed to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of SSCs that have been evaluated. This will ensure that the conclusions that have been drawn from the evaluation remain valid. Further details of acceptable processes for implementation in specific applications are discussed in application-specific regulatory guides (Refs. 6-9).

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

The staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that support the change to the LB. The program should be capable of trending equipment performance after a change has been implemented to demonstrate that performance is consistent with that assumed in the traditional engineering and probabilistic analyses that were conducted to justify the change. This may include monitoring associated with non-safety-related SSCs if the analysis determines those SSCs to be risk significant. The program should be structured such that (1) SSCs are monitored commensurate with their safety importance, i.e., monitoring for SSCs categorized as having low safety significance may be less rigorous than that for SSCs of high safety significance, (2) feedback of information and corrective actions is accomplished in a timely manner, and (3) degradation in SSC performance is detected and corrected before plant safety can be compromised. The potential impact of observed SSC degradation on similar components in different systems throughout the plant should be considered.

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

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

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

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

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

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

As part of the monitoring program, it is important that provisions for specific cause determination, trending of degradation and failures, and corrective actions be included. Such provisions should be applied to SSCs commensurate with their importance to safety as determined by the engineering evaluation that supports the LB change. A determination of cause is needed when performance expectations are not being met or when there is a functional failure of an application-specific SSC that poses a significant condition adverse to performance. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or ensure that it is anticipated prior to becoming a safety concern. It should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications (as defined in Ref. 14).

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

2.4 ELEMENT 4: SUBMIT PROPOSED CHANGE

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

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

In developing the risk information set forth in this regulatory guide, licensees will likely identify SSCs with high risk significance that are not currently subject to regulatory requirements or are subject to a level of regulation that is not commensurate with their risk significance. It is expected that licensees will propose LB changes that will subject these SSCs to an appropriate level of regulatory oversight, consistent with the risk significance of each SSC. Specific information on the staff's expectations in this regard is set forth in the application-specific regulatory guides (Refs. 6-9).

2.5 QUALITY ASSURANCE

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

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

! Use personnel qualified for the analysis.

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

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

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

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

3. DOCUMENTATION

3.1 Introduction

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

3.2 Archival Documentation

Archival documentation should include a detailed description of engineering analyses conducted and the results obtained, irrespective of whether they were quantitative or qualitative, or whether the analyses made use of traditional engineering methods or probabilistic approaches. This documentation should be maintained by the licensee, as part of the normal quality assurance program, so that it is available for examination. Documentation of the analyses conducted to support changes to a plant's LB should be maintained as lifetime quality records in accordance with Regulatory Guide 1.33 (Ref. 15).

3.3 Licensee Submittal Documentation

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

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

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

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

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

- Identification of how and where the proposed change will be documented as part of the plant's LB (e.g., FSAR, technical specifications, licensing conditions). This should include proposed changes or enhancements to the regulatory controls for high-risk-significant SSCs that are not subject to any requirements or the requirements are not commensurate with the SSC's risk significance.

  The licensee should also identify:

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

- SSCs for which requirements should be increased.

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

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

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

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

3.3.1 Risk Assessment Methods

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

- A description of risk assessment methods used,

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

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

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

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

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

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

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

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

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

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

3.3.2 Cumulative Risks

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

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

! The calculated change in risk for each application (CDF and LERF) and the plant elements (e.g., SSCs, procedures) affected by each change,

! Qualitative arguments that were used to justify the change (if any) and the plant elements affected by these arguments;

! Compensatory measures or other commitments used to help justify the change (if any) and the plant elements affected, and

! Summarized results from the monitoring programs (where applicable) and a discussion of how these results have been factored into the PRA or into the current application.

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

3.4 Implementation Plan and Performance Monitoring Documentation

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

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10. W.T. Pratt et al., "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," NUREG/CR-6595, January 1999.[3]

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[1] USNRC SECY papers are available electronically on the NRC's web page at <www.nrc.gov> under Commission's Activities.

[2] Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to <DISTRIBUTION@NRC.GOV>. Active guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161; telephone (703)487-4650; online <http://www.ntis.gov/ordernow>. Copies of active and draft guides are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)4154737 or (800)397-4209; fax (301)415-3548; email <PDR@NRC.GOV>.

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

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~~APPENDIX A~~

~~PRA Characteristics and Attributes~~

~~A.1 INTRODUCTION~~

~~In any regulatory decision, the goal is to make a sound safety decision based on technically defensible information. Therefore, for a regulatory decision relying upon risk insights as one source of information, there needs to be confidence in the PRA results from which the insights are derived. Consequently, the PRA needs to have the requisite scope, level of detail, and technical acceptability to give an appropriate level of confidence in the results used in the regulatory decisionmaking. It is recognized that these aspects can vary depending on the specific decision under consideration.~~

~~Although the minimum technical elements needed to ensure a PRA acceptable to the staff are defined herein they do not, by themselves, ensure confidence in PRA results. This confidence may be gained, however, via the definition and proper use of supporting technical requirements.~~

~~For example, in the Level 1 technical element of systems analysis, one functional attribute is that "the model is developed in sufficient detail to capture the impact of dependencies." To ensure that the intent of this attribute is met, it is necessary to understand the dependencies that could impact the availability and operability of the system and components under consideration. However, what the dependencies are and how they support a specific system or component are not always evident. Dependencies such as the need for DC power for the Reactor Core Isolation Cooling (RCIC) system (in a BWR) are evident. However, for continued operation of RCIC, there is also a need for suppression pool cooling. The steam from the RCIC turbine exhausts to the suppression pool, and loss of cooling to the pool can cause the RCIC turbine to trip on high exhaust pressure. This type of dependency is not as evident. Consequently, to ensure that the PRA has properly accounted for the impact of dependencies, supporting technical requirements interpreting this functional requirement (and the others) are needed. In this example, the supporting requirements may specify the types of dependencies (e.g., motive and control power, design and operational conditions) that need to be considered in looking at the availability and operability of a particular type of component (e.g., turbine-driven pump).~~

~~Consensus PRA standards can be used to define these technical requirements, and an industry peer review program can provide an assessment of the PRA's weaknesses. The staff expects that these standards will be endorsed by NRC.~~

~~A.2 PRA CHARACTERISTICS AND ATTRIBUTES~~

~~Tables A-1 and A-2 provide a summary of the PRA characteristics and attributes acceptable to the staff.~~

~~Table A-1 Summary of Characteristics and Attributes of an Acceptable PRA~~

~~**Element**~~	~~**Desired Characteristics and Attributes**~~
~~PRA Full Power, Low Power, and Shutdown~~	

~~Table A-1 Summary of Characteristics and Attributes of an Acceptable PRA~~

~~**Element**~~	~~**Desired Characteristics and Attributes**~~
~~Level 1 PRA (internal events -- transients and loss of coolant accidents (LOCAs))~~	
~~Initiating Event Analysis~~	• ~~sufficiently detailed identification and characterization of initiators~~ • ~~grouping of individual events according to plant response and mitigating requirements~~ • ~~proper screening of any individual or grouped initiating events~~
~~Success Criteria Analysis~~	• ~~based on best-estimate engineering analyses applicable to the actual plant design and operation~~ • ~~codes developed, validated, and verified in sufficient detail~~ ~~- analyze the phenomena of interest~~ ~~- be applicable in the pressure, temperature, and flow range of interest~~
~~Accident Sequence Development Analysis~~	• ~~defined in terms of hardware, operator action, and timing requirements and desired end states (e.g., core damage or plant damage states)~~ • ~~includes necessary and sufficient equipment (safety and non-safety) reasonably expected to be used to mitigate initiators~~ • ~~includes functional, phenomenological, and operational dependencies and interfaces~~
~~Systems Analysis~~	~~models developed in sufficient detail to:~~ • ~~reflect the as-built, as-operated plant, including how it has performed during the plant history~~ • ~~reflect the required success criteria for the systems to mitigate each identified accident sequence~~ • ~~capture the impact of dependencies, including support systems and harsh environmental impacts~~ • ~~include both active and passive components and failure modes that impact the function of the system~~ • ~~include common cause failures, human errors, unavailability due to test and maintenance, etc.~~
~~Parameter Estimation Analysis~~	• ~~estimation of parameters associated with initiating event, basic event probability models, recovery actions, and unavailability events that account for plant-specific and generic data~~ • ~~consistent with component boundaries~~ • ~~estimation includes a characterization of the uncertainty~~

~~Table A-1 Summary of Characteristics and Attributes of an Acceptable PRA~~

~~**Element**~~	~~**Desired Characteristics and Attributes**~~
~~Human Reliability Analysis~~	• ~~identification and definition of the human failure events that would result in initiating events or pre- and post- accident events that would impact the mitigation of initiating events~~ • ~~quantification of the associated human error probabilities, taking into account scenario- (where applicable) and plant-specific factors and including appropriate dependencies both pre- and post- accident~~
~~Quantification~~	• ~~estimation of the CDF for modeled sequences that are not screened due to truncation, given as a mean value~~ • ~~estimation of the accident sequences CDFs for each initiating event group~~ • ~~truncation values set relative to the total plant CDF such that the frequency is not significantly impacted~~
~~Interpretation of Results Analysis~~	• ~~identification of the key contributors to CDF: initiating events, accident sequences, equipment failures, and human errors~~ • ~~identification of sources of uncertainty and their impact on the results~~ • ~~understanding of the impact of the key assumptions* on the CDF and the identification of the accident sequence and their contributors~~
~~Level 2 PRA~~	
~~Plant Damage State Analysis~~	• ~~identification of the attributes of the core damage scenarios that influence severe accident progression, containment performance, and any subsequent radionuclide releases~~ • ~~grouping of core damage scenarios with similar attributes into plant damage states~~ • ~~carryover of relevant information from Level 1 to Level 2~~
~~Severe Accident Progression Analysis~~	• ~~use of verified, validated codes by qualified trained users with an understanding of the code limitations and the means for addressing the limitations~~ • ~~assessment of the credible severe accident phenomena via a structured process~~ • ~~assessment of containment system performance, including linkage with failure modes on non-containment systems~~ • ~~establishment of the capacity of the containment to withstand severe accident environments~~ • ~~assessment of accident progression timing, including timing of loss of containment failure integrity~~

~~Table A-1 Summary of Characteristics and Attributes of an Acceptable PRA~~

~~**Element**~~	~~**Desired Characteristics and Attributes**~~
~~Quantification~~	• ~~estimation of the frequency of different containment failure modes and resulting radionuclide source terms~~
~~Source Term Analysis~~	• ~~assessment of radionuclide releases, including appreciation of timing, location, amount and form of release~~ • ~~grouping of radionuclide releases into smaller subset of representative source terms with emphasis on large early release (LER) and on large late release (LLR)~~
~~Interpretation of Results Analysis~~	• ~~identification of the contributors to containment failure and resulting source terms~~ • ~~identification of sources of uncertainty and their impact on the results~~ • ~~understanding of the impact of the key assumptions* on Level 2 results~~
~~Documentation~~	
~~Traceability and defensibility~~	• ~~the documentation is sufficient to facilitate independent peer reviews~~ • ~~the documentation describes all the important interim and final results, insights, and important sources of uncertainties~~ • ~~walkdown process and results are fully described~~
~~*Assumptions include those decisions and judgments that were made in the course of the analysis.~~	

~~In addressing the above elements, because of the nature and impact of internal flood and fire and external hazards, their attributes need to be discussed separately. This is because flood, fire, and external hazards analyses have the ability to cause initiating events but also have the capability to impact the availability of mitigating systems. Therefore, in developing the PRA model, the impact of flood, fire, and external hazards needs to be considered in each of the above technical elements. Table A-2 provides a summary of the desired attributes of an acceptable internal flood, fire and external hazards analysis.~~

~~Table A-2 Summary of Characteristics and Attributes of an Acceptable Internal Flood and Fire Analysis and External Hazards Analysis~~

~~Areas of Analysis~~	~~Desired Characteristics and Attributes*~~
~~Internal Flood Analysis~~	

~~Table A-2 Summary of Characteristics and Attributes of an Acceptable Internal Flood and Fire Analysis and External Hazards Analysis~~

~~Areas of Analysis~~	~~Desired Characteristics and Attributes*~~
~~Flood Identification Analysis~~	• ~~sufficiently detailed identification and characterization of:~~ ~~- flood areas and SSCs located within each area~~ ~~- flood sources and flood mechanisms~~ ~~- type of water release and capacity~~ ~~- structures functioning as drains and sumps~~ • ~~verification of the information through plant walkdowns~~
~~Flood Evaluation Analysis~~	• ~~identification and evaluation of~~ ~~- flood propagation paths~~ ~~- flood-mitigating plant design features and operator actions~~ ~~- susceptibility of SSCs in each flood area to the different types of floods~~ • ~~elimination of flood scenarios uses well defined and justified screening criteria~~
~~Quantification~~	• ~~identification of flooding-induced initiating events on the basis of a structured and systematic process~~ • ~~estimation of flooding-initiating event frequencies~~ • ~~estimation of CDF for chosen flood scenarios~~ • ~~modification of the Level 1 models to account for flooding effects, including uncertainties~~
~~Internal Fire Analysis~~	
~~Fire Area Identification and Screening Analysis~~	• ~~all potentially risk-significant fire areas are identified and addressed~~ • ~~all required mitigating components and their cables in each fire area are identified~~ • ~~screening criteria are defined and justified~~ • ~~necessary walkdowns are performed to confirm the screening decisions~~ • ~~screening process and results are documented~~ • ~~unscreened events areas are subjected to appropriate level of evaluations (including detailed fire PRA evaluations as described below) as needed~~
~~Fire Initiation Analysis~~	• ~~all potentially significant fire scenarios in each unscreened area are addressed~~ • ~~fire scenario frequencies reflect plant-specific features~~ • ~~fire scenario physical characteristics are defined~~ • ~~bases are provided for screening fire initiators~~

~~Table A-2 Summary of Characteristics and Attributes of an Acceptable Internal Flood and Fire Analysis and External Hazards Analysis~~

~~Areas of Analysis~~	~~Desired Characteristics and Attributes*~~
~~Fire Growth and Damage Analysis~~	• ~~damage to all potentially significant components is addressed; considers all potential component failure modes~~ • ~~all potentially significant damage mechanisms are identified and addressed; damage criteria are specified~~ • ~~analysis addresses scenario-specific factors affecting fire growth, suppression, and component damage~~ • ~~models and data are consistent with experience from actual fire experience as well as experiments~~ • ~~includes evaluation of propagation of fire and fire effects (e.g., smoke) between fire compartments~~
~~Plant Response Analysis~~	• ~~all potentially significant fire-induced initiating events are addressed; the bases for the fire-induced initiating events are included in the model~~ • ~~includes fire scenario impacts on core damage mitigation and containment systems, including fire-induced failures~~ • ~~analysis reflects plant-specific safe shutdown strategy~~ • ~~potential circuit interactions that can interfere with safe shutdown are addressed~~ • ~~human reliability analysis addresses effect of fire scenario-specific conditions on operator performance~~
~~Quantification~~	• ~~estimation of CDF for chosen fire scenarios~~ • ~~identification of sources of uncertainty and their impact on the results~~ • ~~understanding of the impact of the key assumptions** on the CDF~~ • ~~all fire risk-significant sequences are traceable and reproducible~~
~~External Hazards Analysis~~	
~~Screening and Bounding Analysis~~	• ~~credible external events (natural and man-made) that may affect the site are addressed~~ • ~~screening and bounding criteria are defined and results are documented~~ • ~~necessary walkdowns are performed~~ • ~~non-screened events are subjected to appropriate level of evaluations~~
~~Hazard Analysis~~	• ~~the hazard analysis is site- and plant-specific~~ • ~~the hazard analysis addresses uncertainties~~

~~Table A-2 Summary of Characteristics and Attributes of an Acceptable Internal Flood and Fire Analysis and External Hazards Analysis~~

~~Areas of Analysis~~	~~Desired Characteristics and Attributes*~~
~~Fragility Analysis~~	• ~~fragility estimates are plant-specific for important SSCs~~ • ~~walkdowns are conducted to identify plant-unique conditions, failure modes, and as-built conditions.~~
~~Level 1 Model Modification~~	• ~~important external-event-caused initiating events that can lead to core damage and large early release are included~~ • ~~external-event-related unique failures and failure modes are incorporated~~ • ~~equipment failures from other causes and human errors are included. When necessary, human error data is modified to reflect unique circumstances related to the external event under consideration~~ • ~~unique aspects of common causes, correlations, and dependencies are included~~ • ~~the systems model reflects as-built, as-operated plant conditions~~ • ~~the integration/quantification accounts for the uncertainties in each of the inputs (i.e., hazard, fragility, system modeling) and final quantitative results such as CDF and LERF~~ • ~~the integration/quantification accounts for all dependencies and correlations that affect the results~~
~~*Documentation also applies to flood, fire and external hazards.~~ ~~**Assumptions include those decisions and judgments that were made in the course of the analysis.~~	

~~Additional descriptions of the characteristics and attributes in Tables A-1 and A-2 follow.~~

~~Level 1 PRA (Internal Events)~~

~~Initiating event analysis identifies and characterizes those random internal events that both challenge normal plant operation during power or shutdown conditions and require successful mitigation by plant equipment and personnel to prevent core damage from occurring. Events that have occurred at the plant and those that have a reasonable probability of occurring are identified and characterized. An understanding of the nature of the events is performed such that a grouping of the events into event classes, with the classes defined by similarity of system and plant responses (based on the success criteria), may be performed to manage the large number of potential events that can challenge the plant.~~

~~Success criteria analysis determines the minimum requirements for each function (and ultimately the systems used to perform the functions) needed to prevent core damage (or to mitigate a release) if an initiating event occurs. The requirements defining the success criteria are based on acceptable engineering analyses that represent the design and operation of the plant under consideration. The criteria needed for a function to be successful are dependent on the initiator and the conditions created by the initiator. The code(s) used to perform the analyses for~~

~~developing the success criteria are validated and verified for both technical integrity and suitability to assess plant conditions for the reactor pressure, temperature, and flow range of interest, and to accurately analyze the phenomena of interest. Calculations are performed by personnel qualified to perform the types of analyses of interest and are well trained in the use of the code(s).~~

~~Accident sequence development analysis models, chronologically, the different possible progression of events (i.e., accident sequences) that can occur from the start of the initiating event to either successful mitigation or to core damage. The accident sequences account for those systems and operator actions that are used (and available) to mitigate the initiator based on the defined success criteria and plant operating procedures (e.g., plant emergency and abnormal operating procedures and as practiced in simulator exercises). The availability of a system includes consideration of the functional, phenomenological, and operational dependencies and interfaces among the different systems and operator actions during the course of the accident progression.~~

~~Systems analysis identifies the different combinations of failures that can preclude the ability of the system to perform its function as defined by the success criteria. The model representing the various failure combinations includes, from an as-built and as-operated perspective, the system hardware and instrumentation (and their associated failure modes) and the human failure events that would prevent the system from performing its defined function. The basic events representing equipment and human failures are developed in sufficient detail in the model to account for dependencies among the different systems, as well as to distinguish the specific equipment or human event (and its failure mechanism) that has a major impact on the system's ability to perform its function.~~

~~Parameter estimation analysis quantifies the frequencies of the identified initiators and quantifies the equipment failure probabilities and equipment unavailabilities of the modeled systems. The estimation process includes a mechanism for addressing uncertainties, has the ability to combine different sources of data in a coherent manner, and represents the actual operating history and experience of the plant and applicable generic experience as applicable.~~

~~Human reliability analysis identifies and provides probabilities for the human failure events that can negatively impact normal or emergency plant operations. The human failure events associated with normal plant operation include those events that leave the system (as defined by the success criteria) in an unrevealed, unavailable state. The human failure events associated with emergency plant operation include those events that, if not performed, do not allow the needed system to function. Quantification of the probabilities of these human failure events is based on plant- and accident-specific conditions, where applicable, including any dependencies among actions and conditions.~~

~~Quantification provides an estimation of the CDF given the design, operation, and maintenance of the plant. This CDF is based on the summation of the estimated CDF from each initiator class. If truncation of accident sequences and cutsets is applied, truncation limits are set so that the overall model results are not impacted significantly and that important accident sequences are not eliminated. Therefore, the truncation limit can vary for each accident sequence. Consequently, the truncation value is selected so that the accident sequence CDF before and after truncation only differs by less than one significant figure.~~

~~Interpretation of results entails examining and understanding the results of the PRA and identifying the important contributors sorted by initiating events, accident sequences, equipment failures, and~~

~~human errors. Methods such as importance measure calculations (e.g., Fussell-Vesely, risk achievement, risk reduction, and Birnbaum) are used to identify the contributions of various events to the model estimation of core damage frequency for both individual sequences and the model as a total. Sources of uncertainty are identified and their impact on the results analyzed. The sensitivity of the model results to model boundary conditions and other key assumptions is evaluated using sensitivity analyses to look at key assumptions both individually or in logical combinations. The combinations analyzed are chosen to fully account for interactions among the variables.~~

~~Level 2 PRA (Containment Response)~~

~~Plant damage state analysis groups similar core damage scenarios together to allow a practical assessment of the severe accident progression and containment response resulting from the full spectrum of core damage accidents identified in the Level 1 analysis. The plant damage state analysis defines the attributes of the core damage scenarios that represent important boundary conditions to the assessment of severe accident progression and containment response that ultimately affect the resulting source term. The attributes address the dependencies between the containment systems modeled in the Level 2 analysis with the core damage accident sequence models to fully account for mutual dependencies. Core damage scenarios with similar attributes are grouped together to allow for efficient evaluation of the Level 2 response.~~

~~Severe accident progression analysis models the different series of events that challenge containment integrity for the core damage scenarios represented in the plant damage states. The accident progressions account for interactions among severe accident phenomena and system and human responses to identify credible containment failure modes including failure to isolate the containment. The timing of major accident events and the subsequent loadings produced on the containment are evaluated against the capacity of the containment to withstand the potential challenges. The containment performance during the severe accident is characterized by the timing (e.g., early versus late), size (e.g., catastrophic versus bypass), and location of any containment failures. The code(s) used to perform the analysis are validated and verified for both technical integrity and suitability. Calculations are performed by personnel qualified to perform the types of analyses of interest and well trained in the use of the code(s).~~

~~Quantification integrates the accident progression models and source term evaluation to provide estimates of the frequency of radionuclide releases that could be expected following the identified core damage accidents. This quantitative evaluation reflects the different magnitudes and timing of radionuclide releases and specifically allows for identification of the LERF and the probability of a large late release.~~

~~Source term analysis characterizes the radiological release to the environment resulting from each severe accident sequence leading to containment failure or bypass. The characterization includes the time, elevation, and energy of the release and the amount, form, and size of the radioactive material that is released to the environment. The source term analysis is sufficient to determine whether a large early release or a large late release occurs. A large early release is one involving significant, unmitigated releases from containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure at or shortly after vessel breach, containment bypass events, and loss of containment isolation. With large late release, significant, unmitigated release from containment occurs in a time frame that allows effective evacuation of the close-in population such that early fatalities are unlikely.~~

~~Interpretation of results entails examining results from importance measure calculations (e.g., Fussel-Vesely, risk achievement, risk reduction, and Birnbaum) to identify the contributions of various events to the model estimation of LERF and large late release probability for both individual sequences and the model as a total. Sources of uncertainty are identified and their impact on the results analyzed. The sensitivity of the model results to model boundary conditions and other key assumptions is evaluated using sensitivity analyses to look at key assumptions both individually or in logical combinations. The combinations analyzed are chosen to fully account for interactions among the variables.~~

~~Internal Floods~~

~~Flood identification analysis identifies those plant areas where flooding could pose significant risk. Flooding areas are defined on the basis of physical barriers, mitigation features, and propagation pathways. For each flooding area, flood sources that are due to equipment (e.g., piping, valves, pumps) and other sources internal to the plant (e.g., tanks) are identified along with the affected SSCs. Flooding mechanisms are examined that include failure modes of components, human-induced mechanisms, and other water releasing events. Flooding types (e.g., leak, rupture, spray) and flood sizes are determined. Plant walkdowns are performed to verify the accuracy of the information.~~

~~Flood evaluation analysis identifies the potential flooding scenarios for each flood source by identifying flood propagation paths of water from the flood source to its accumulation point (e.g., pipe and cable penetrations, doors, stairwells, failure of doors or walls). Plant design features or operator actions that have the ability to terminate the flood are identified. Credit given for flood isolation is justified. The susceptibility of each SSC in a flood area to flood-induced mechanisms is examined (e.g., submerge, spray, pipe whip, and jet impingement). Flood scenarios are developed by examining the potential for propagation and giving credit for flood mitigation. Flood scenarios can be eliminated on the basis of screening criteria. The screening criteria used are well defined and justified.~~

~~Quantification provides an estimation of the CDF of the plant that is due to internal floods. The frequency of flooding-induced initiating events that represent the design, operation, and experience of the plant is quantified. The Level 1 models are modified and the internal flood accident sequences quantified: (1) modify accident sequence models to address flooding phenomena, (2) perform necessary calculations to determine success criteria for flooding mitigation, (3) perform parameter estimation analysis to include flooding as a failure mode, (4) perform human reliability analysis to account for performance-shaping factors that are due to flooding, and (5) quantify internal flood accident sequence CDF. Modification of the Level 1 models is performed consistent with the characteristics for Level 1 elements for transients and LOCAs. In addition, sources of uncertainty are identified and their impact on the results analyzed. The sensitivity of the model results to model boundary conditions and other key assumptions is evaluated using sensitivity analyses to look at key assumptions both individually or in logical combinations. The combinations analyzed are chosen to fully account for interactions among the variables.~~

~~Internal Fire~~

~~Screening analysis identifies fire areas where fires could pose a significant risk. Fire areas that are not risk significant can be "screened out" from further consideration in the PRA analysis. Both qualitative and quantitative screening criteria can be used. The former address whether an unsuppressed fire in the area poses a nuclear safety challenge; the latter are compared against a bounding assessment of the fire-induced CDF for the area. The potential for fires involving~~

~~multiple areas should be addressed. Assumptions used in the screening analysis should be verified through appropriate plant walkdowns. Key screening analysis assumptions and results, e.g., the area-specific conditional core damage probabilities (assuming fire-induced loss of all equipment in the area), should be documented.~~

~~Fire initiation analysis determines the frequency and physical characteristics of the detailed (within-area) fire scenarios analyzed for the unscreened fire areas. The analysis needs to identify a range of scenarios that will be used to represent all possible scenarios in the area. The possibility of seismically induced fires should be considered. The scenario frequencies should reflect plant-specific experience and should be quantified in a manner that is consistent with their use in the subsequent fire damage analysis (discussed below). The physical characterization of each scenario should also be in terms that will support the fire damage analysis (especially with respect to fire modeling).~~

~~Fire damage analysis determines the conditional probability that sets of potentially risk-significant components (including cables) will be damaged in a particular mode, given a specified fire scenario. The analysis needs to address components whose failure will cause an initiating event, affect the plant's ability to mitigate an initiating event, or affect potentially risk-significant equipment (e.g., through suppression system actuation). Damage from heat, smoke, and exposure to suppressants should be considered. If fire models are used to predict fire-induced damage, compartment-specific features (e.g., ventilation, geometry) and target-specific features (e.g., cable location relative to the fire) should be addressed. The fire suppression analysis should account for the scenario-specific time required to detect, respond to, and extinguish the fire. The models and data used to analyze fire growth, fire suppression, and fire-induced component damage should be consistent with experience from actual nuclear power plant fire experience as well as experiments.~~

~~Plant response analysis involves the modification of appropriate plant transient and LOCA PRA models to determine the conditional core damage probability, given damage to the set(s) of components defined in the fire damage analysis. All potentially significant fire-induced initiating events, including such "special" events as loss of plant support systems and interactions between multiple nuclear units during a fire event, should be addressed. The analysis should address the availability of non-fire affected equipment (including control) and any required manual actions. For fire scenarios involving control room abandonment, the analysis should address the circuit interactions raised in NUREG/CR-5088,[1] including the possibility of fire-induced damage prior to transfer to the alternative shutdown panel(s). The human reliability analysis of operator actions should address fire effects on operators (e.g., heat, smoke, loss of lighting, effect on instrumentation) and fire-specific operational issues (e.g., fire response operating procedures, training on these procedures, potential complications in coordinating activities). In addition, sources of uncertainty are identified and their impact on the results analyzed. The sensitivity of the model results to model boundary conditions and other key assumptions is evaluated using sensitivity analyses to look at key assumptions both individually or in logical combinations. The combinations analyzed are chosen to fully account for interactions among the variables.~~

~~External Hazards~~

~~Screening and bounding analysis identifies external events other than earthquake that may challenge plant operations and require successful mitigation by plant equipment and personnel to~~

[1] "Fire Risk Scoping Study: Investigation of Nuclear Power Plant Risk Including Previously Unaddressed Issues, NUREG/CR-5088, January 1989.

~~prevent core damage from occurring. The term "screening out" is used here for the process whereby an external event is excluded from further consideration in the PRA analysis. There are two fundamental screening criteria embedded in the requirements here: An event can be screened out either (1) if it meets the design criteria, or (2) if it can be shown using an analysis that the mean value of the design basis hazard used in the plant design is less than 10^{-5}/year, and that the conditional core-damage probability is less than 10^{-1}, given the occurrence of the design basis hazard. An external event that cannot be screened out using either of these criteria is subjected to the detailed-analysis.~~

~~Hazard analysis characterizes non-screened external events and seismic events, generally, as frequencies of occurrence of different sizes of events (e.g., earthquakes with various peak ground accelerations, hurricanes with various maximum wind speeds) at the site. The external events are site-specific and the hazard characterization addresses both aleatory and epistemic uncertainties.~~

~~Fragility analysis characterizes the conditional probability of failure of important SSCs whose failure may lead to unacceptable damage to the plant (e.g., core damage) given occurrence of an external event. For important SSCs, the fragility analysis is realistic and plant-specific. The fragility analysis is based on extensive plant-walkdowns reflecting as-built, as-operated conditions.~~

~~Level 1 model modification assures that the system models include all important external-event-caused initiating events that can lead to core damage or large early release. The system model includes external-event-induced SSC failures, non-external-event-induced failures (random failures), and human errors. The system analysis is well coordinated with the fragility analysis and is based on plant walkdowns. The results of the external event hazard analysis, fragility analysis, and system models are assembled to estimate frequencies of core damage and large early release. Uncertainties in each step are propagated through the process and displayed in the final results. The quantification process is capable of conducting necessary sensitivity analysis and to identify dominant sequences and contributors.~~

~~Documentation~~

~~Traceability and defensibility provide the necessary information such that the results can easily be reproduced and justified. The sources of information used in the PRA are both referenced and retrievable. The methodology used to perform each aspect of the work is described either through documenting the actual process or through reference to existing methodology documents. Assumptions[2] made in performing the analyses are identified and documented along with their justification to the extent that the context of the assumption is understood. The results (e.g., products and outcomes) from the various analyses are documented.~~

[2] ~~Assumptions include those decisions and judgments that were made in the course of the analysis.~~

~~A.3 PEER REVIEW~~

~~A peer review process can be used to identify weaknesses in the PRA and the importance of the weaknesses to the confidence in the PRA results. An acceptable peer review needs to be performed by qualified personnel, needs to be performed according to an established process that compares the PRA against desired characteristics and attributes, needs to document the results, and needs to identify both strengths and weaknesses of the PRA.~~

~~Table A-3 provides a summary of desired characteristics and attributes of a peer review.~~

~~Table A-3 Summary of Desired Characteristics and Attributes of a Peer Review~~

~~Element~~	~~Desired Characteristics and Attributes~~
~~Team Qualifications~~	• ~~independent with no conflicts of interest~~ • ~~expertise in all the technical elements of a PRA, including integration~~ • ~~knowledge of the plant design and operation~~ • ~~knowledge of the peer review process~~
~~Peer Review Process~~	• ~~is a documented process~~ • ~~uses a set of desired PRA characteristics and attributes~~ • ~~reviews PRA methods~~ • ~~reviews application of methods~~ • ~~reviews key assumptions~~ • ~~determines if PRA represents as-built and as-operated plant~~ • ~~reviews results of each PRA technical element for reasonableness~~ • ~~reviews PRA maintenance and update process~~
~~Documentation~~	• ~~describes the peer review team qualifications~~ • ~~describes the peer review process~~ • ~~documents where PRA does not meet desired characteristics and attributes~~ • ~~assesses and documents significance of deficiencies~~

~~The team qualifications determine the credibility and acceptability of the peer reviewers. In order that the peer reviewers not give any perception of a technical conflict of interest, they should not have performed any actual work on the PRA. The members of the peer review team have technical expertise in the PRA elements they review, including experience in the specific methods that are used to perform the PRA elements. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review. In addition, knowledge of the key features specific to the plant design and operation is essential. Finally, each member of the peer review team is knowledgeable of the peer review process, including the desired characteristics and attributes used to assess the acceptability of the PRA.~~

~~The peer review process includes a documented procedure to direct the team in evaluating the acceptability of a PRA. The review process compares the PRA against the desired PRA characteristics and attributes that are listed in this appendix and elaborated on in a PRA standard. In addition to reviewing the methods used in the PRA, the peer review also determines whether the application of those methods was done correctly. The PRA models are compared against the plant design and procedures to validate that they reflect the as-built and as-operated plant. Key assumptions are reviewed to determine whether they are appropriate and whether they have a significant impact on the PRA results. The PRA results are checked for fidelity with the model structure and also for consistency with the results from PRAs for similar plants. Finally, the peer review process examines the procedures or guidelines in place for updating the PRA to reflect changes in plant design, operation, or experience.~~

~~Documentation provides the necessary information such that the peer review process and the findings are both traceable and defensible. Descriptions of the qualifications of the peer review team members and the peer review process are documented. The results of the peer review for each technical element and the PRA update process are described, including those areas in which the PRA does not meet or exceed the desired characteristics and attributes used in the review process. This includes an assessment of the importance of any identified deficiencies on the PRA results and potential uses and how these deficiencies were addressed and resolved.~~

~~A.4 INTEGRATED DECISIONMAKING PANEL~~

~~Instances when the PRA may not appear to meet all significant elements that are considered important to the decision at hand typically benefit from the use of an integrated decisionmaking panel. In this instance, the panel would attempt to establish an appreciation of, and compensation for, either the uncertainty or potential inadequacy in relation to the specific application for which the PRA is planned. They would essentially try to establish the role the PRA results would play in the decision commensurate with their level of confidence in those results. If the panel approach is chosen, there are certain characteristics and attributes that the PRA should have.~~

~~Table A-4 provides a summary of the required characteristics and attributes of an integrated decisionmaking panel.~~

~~Table A-4 Summary of Desired Characteristics and Attributes of an Integrated Decisionmaking Panel To Use PRA Results~~

~~Element~~		**~~Desired Characteristics and Attributes~~**
~~Panel Member Qualifications~~		• ~~diverse membership, including PRA, engineering, operations, etc.~~ • ~~wide knowledge of plant~~ • ~~broad understanding of how changes in requirements and issues could affect SSC response~~ • ~~training~~
~~Panel process~~	~~Decision-making Process~~	• ~~decisionmaking process appropriate~~ • ~~appropriate information available~~ • ~~evaluation of risk significance represents appropriate consideration of issues~~

~~Table A-4 Summary of Desired Characteristics and Attributes of an Integrated Decisionmaking Panel To Use PRA Results~~

~~**Element**~~		~~**Desired Characteristics and Attributes**~~
	~~Technical Information Bases~~	• ~~adequate for the scope of the analysis~~
	~~Incorporation of non-PRA Modeled Items~~	• ~~evaluate in a systematic manner the safety significance of items not modeled in the PRA but affected by a proposed application (e.g., SSCs, modes of operation)~~
	~~Identification of Limitations~~	• ~~process applied by the licensee to overcome limitations of PRA is appropriate~~ • ~~decisions made that do not follow straightforwardly from the PRA need a technical basis that shows how the PRA information and the supplementary information validly combine to support the finding~~ • ~~no findings contradict the PRA in a fundamental way~~
~~Documentation~~		• ~~written procedure of the panel process~~ • ~~report of the decision concluded by the panel and the basis for the conclusion~~

~~Panel member qualifications identify the credentials needed of the panel members such that decisions reached by the panel are technically defensible. The panel includes members with diverse backgrounds such as PRA, engineering, and operations. Plant members have a wide knowledge of the plant and a broad understanding of how changes in requirements and issues could affect SSC response. Training is provided to the members for the activities they are required to perform. This training is of sufficient depth such that the member can make informed decisions by combining multiple, diverse knowledge sets.~~

~~The decisionmaking process is based on a written, systematic approach and shown to be appropriate for the decisions the panel is needed to render. The necessary technical information is made available to the panel and is examined to allow the applicable issues to be raised. The issues are disposed of using a systematic and defensible process, and documentation of findings made by the panel are traceable and reviewable. Any evaluation of the risk significance of issues appropriately considers probabilistic information, traditional engineering evaluations, sensitivity studies, operational experience, engineering judgment, and current regulatory requirements.~~

~~The technical information bases provide the necessary information for the panel to arrive at a defensible decision. This information is derived from various sources, including, for example, simplified or detailed engineering analyses, specific plant-operational expertise, and expert opinion, and is shown to be adequate for the scope of the analysis. Therefore, the technical information used is sufficient to allow analysis (e.g., quantification) of both success and failure scenarios to (1) identify the roles played by the SSCs, and (2) establish the safety significance of~~

~~the SSCs, as well as to identify causal models to be used to establish the effects of any proposed changes.~~

~~Incorporation of non-PRA modeled items involves evaluating the safety significance of items not modeled in the PRA but affected by a proposed application. This systematic evaluation consists of searching for items that might contribute to initiating event occurrence, identifying mitigating system items that were not modeled in the PRA because their failure was not expected to dominate system failure in the baseline configuration, and recognizing items in systems that do not play a direct role in accident mitigation but do interface with accident mitigating systems.~~

~~Identification of limitations specifies those aspects in the PRA that decrease the level of confidence in the results, and consequently, are to be addressed by the integrated decisionmaking panel process. These deficiencies may exist because (1) an item was not modeled in the PRA, (2) an item was inappropriately modeled, or (3) technology was inadequate to model in the PRA. The process used by the integrated decisionmaking panel to resolve the deficiency is based the type of deficiency identified and includes (1) modeling the item in the PRA or accounting for the effects of the item by other means (e.g., using surrogate components), (2) revising the PRA model to appropriately model the item, or (3) soliciting and using expert opinion to resolve items involving a lack of technology. When a decision is made by the panel that does not follow straightforwardly from the PRA, a technical basis is provided that shows how the PRA information and the supplementary information validly combine to support the finding. Further, no findings by the panel can contradict the PRA in a fundamental way.~~

~~Documentation provides the necessary information such that the integrated decisionmaking panel process and its findings are both traceable and defensible. The documentation includes a description of the qualifications of each panel member, the written procedures employed by the panel, and a report of any decisions made by the panel, including the basis for the conclusions.~~

APPENDIX ~~B~~A

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

INTRODUCTION

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

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

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

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

TECHNICAL ISSUES ASSOCIATED WITH THE USE OF IMPORTANCE MEASURES

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

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

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

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

Risk Metrics: The licensee should ensure that risk in terms of both CDF and LERF is considered in the ranking process.

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

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

Sensitivity Analysis for Common Cause Failures: CCFs are modeled in PRAs to account for dependent failures of redundant components within a system. The licensee should determine that the safety-significant categorization has taken into account the combined effect of associated basic PRA events, such as failure to start and failure to run, including indirect contributions through associated CCF event probabilities. CCF probabilities can affect PRA results by enhancing or obscuring the importance of components. A component may be ranked as a high risk contributor mainly because of its contribution to CCFs, or a component may be ranked as a low risk contributor mainly because it has negligible or no contribution to CCFs.

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

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

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

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

Relationship of Importance Measures to Risk Changes: Importance measures do not directly relate to changes in risk. Instead, the risk impact is indirectly reflected in the choice of the value of the measure used to determine whether an SSC should be classified as being of high and low safety significance. This is a concern whether importances are evaluated at the component or at the group level. The PSA Applications Guide suggested values of Fussell-Vesely importance of 0.05 at the system level and 0.005 at the component level, for example. However, the criteria for categorization into low and high significance should be related to the acceptance criteria for changes in CDF and LERF. This implies that the criteria should be a function of the base case

CDF and LERF rather than being fixed for all plants. Thus the licensee should demonstrate how the chosen criteria are related to, and conform with, the acceptance guidelines described in this document. If component-level criteria are used, they should be established taking into account that the allowable risk increase associated with the change should be based on simultaneous changes to all members of the category.

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

REGULATORY ANALYSIS

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

~~**Proposed Revision 1 to**~~

STANDARD REVIEW PLAN CHAPTER 19
Revision 1

19.0 Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance

INTRODUCTION

This chapter of the Standard Review Plan (SRP) identifies the roles and responsibilities of organizations in the U.S. Nuclear Regulatory Commission (NRC) that participate in risk-informed reviews of licensees' proposals for changes to the licensing basis (LB)[1] of nuclear power plants. The SRP identifies the types of information that may be used in fulfilling an organization's responsibilities and provides general guidance on how the information from a probabilistic risk assessment (PRA) can be combined with other pertinent information in the process of making a regulatory decision.

The guidance in this document is a logical extension of current NRC policy on the use of PRA in regulatory activities which is documented in the Commission's PRA policy statement and implementation plan (Refs. 1-3). In developing this SRP chapter, the staff considered the NRC's guidance on the use of PRA in risk-informed regulatory applications as documented in Regulatory Guide (RG) 1.174 (Ref. 4) as well as the relevant industry guidance documented by the Electric Power Research Institute (EPRI) in its "Probabilistic Safety Assessment (PSA) Applications Guide" (Ref. 6). In addition, this chapter references other SRP chapters that provide additional guidance for reviewing specific applications of PRA in regulated activities.

[1] These are modifications to a plant's design, operations 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.

In the process of risk-informed decisionmaking, the NRC will rely on the approach discussed in this chapter. Above all, the design, construction, and operational practices of each plant are expected to be consistent with its LB. In addition, the risk evaluations performed to justify regulatory changes are expected to realistically reflect these plant-specific design, construction, and operational practices. The PRA analyses should be as realistic as practicable and, when interpreting the results of those analyses, the staff should account for the impact of the most significant uncertainties. The results of these risk analyses will then form part of the input to the decisionmaking process that evaluates the margin in plant capability (in both performance and redundancy/diversity). Specifically, the decisionmaking process will use the results of the risk analyses in a manner that complements traditional engineering approaches, supports the defense-in-depth philosophy, and preserves safety margins. Thus, risk analysis will inform, but it will not determine regulatory decisions.

REVIEW RESPONSIBILITIES

The technical nature of a licensee's request will determine which technical review branch in the NRC's Office of Nuclear Reactor Regulation (NRR) will serve as the primary review branch and as such, has overall responsibility for leading the technical review, drafting the staff safety evaluation report (SER) or other appropriate regulatory document, and coordinating input from other technical review organizations. In addition, the following organizations will normally play a role in reviewing risk-informed proposals:

- The Probabilistic Safety Assessment Branch (SPSB) assists the primary review branch (upon request) by reviewing the PRA information and findings submitted by the licensee. Review support includes assessing the adequacy of the scope, level of detail, and quality of the PRA used by the licensee to support the regulatory change, as well as applying risk-related acceptance guidelines to support decisionmaking.

- The Reactor Systems Branch (SRXB) assists the primary review branch or SPSB (upon request) by providing support for accident sequence modeling, including treatment of reactivity and thermal-hydraulic phenomena, system response, and the implementation of emergency and abnormal operating procedures.

- The Operator Licensing, Human Performance and Plant Support Branch (IOLB) holds the primary responsibility for reviewing evaluations of radionuclide contamination or public health effects submitted by a licensee in support of a request for regulatory action.

- The Office of Nuclear Regulatory Research (RES) assists the primary review branch (upon request) by providing technical support in areas involving all aspects of PRA, severe accident phenomenology, and engineering studies.

- The Regional Offices assist the primary review branch (upon request) by providing information on licensees' operational experience in areas of system performance, operator performance, risk management practices, and management controls.

I. AREAS OF REVIEW

The NRC's PRA Implementation Plan as proposed in Ref. 3, now replaced by the Risk-Informed Regulation Implementation Plan (see Ref. 5), identifies a wide scope of regulatory activities for which PRA provides valuable insights. This scope includes activities that require NRC review and approval, as well as other activities that are considered internal to the NRC and affect licensees and applicants in a less direct manner (e.g., generic issue prioritization). This SRP chapter solely concerns licensing amendment requests submitted for NRC review and approval for which PRA can play an effective role in the decisionmaking process. General review guidance for applicable activities is presented in this SRP chapter. In addition, application-specific SRP chapters are available to provide additional guidance for several activities including the following examples:

- changes to allowed outage times (AOTs) and surveillance test intervals (STIs) in plant-specific technical specifications (SRP Chapter 16.1)

- changes in the scope and frequency of tests on pumps and valves in a licensee's inservice test (IST) program (SRP Chapter 3.9.7)

- changes in the scope and frequency of inspections in a licensee's inservice inspection (ISI) program (draft SRP Chapter 3.9.8)

RG 1.174 defines an acceptable approach for use in analyzing and evaluating proposed LB changes. This approach supports the staff's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived through the use of PRA methods) on the risk significance of the proposed changes. The decisionmaking process leading to the proposed change is expected to follow an integrated approach (considering traditional engineering and risk information) and may build upon qualitative factors as well as quantitative analyses and information.

As discussed later in this section, the scope of the staff review of a risk-informed application will depend on the specifics of the application. However, this scope should include reviewing the four elements suggested in Section 2 of RG 1.174. The areas of review for each of these elements are summarized as follows:

- **Element 1 - Define the Proposed Change**: The objective of this element is to lay the groundwork for evaluating the safety impacts of the proposed change. Therefore, one area of review would be an evaluation of the proposed change in light of the LB (i.e., evaluation of the structures, systems, and components (SSCs), as well as the plant procedures and activities that are affected by the proposed change and how these SSCs, procedures or activities relate to the LB). In addition, an evaluation of the method of analysis and a study of available insights from traditional and probabilistic engineering studies that are relevant to the proposed change would be necessary to determine if the change can be supported.

- **Element 2 - Conduct Engineering Evaluations**: The licensees' decisionmaking process should factor in the appropriate traditional and probabilistic engineering insights. Reviewers should evaluate the proposed change to ensure that the defense-in-depth philosophy and sufficient safety margins are maintained, and that the calculated change in plant risk is within the guidelines specified in RG 1.174. Reviewers should also verify that insights from the engineering evaluations used to justify a change have been used to improve operational and engineering decisions where appropriate, and not simply to eliminate requirements the licensee sees as undesirable.

- **Element 3 - Develop Implementation and Monitoring Strategies**: Results from implementation and monitoring strategies can provide an early indication of unanticipated degradation of performance of those plant elements affected by the proposed change. These strategies are therefore important in applications where uncertainty in evaluation models and/or data used to justify the change can change the conclusions of the analysis.

As such, the review scope should include provisions to ensure that the licensee has proposed an implementation and monitoring process that is adequate to (in part) account for uncertainties regarding plant performance under the proposed change.

- **Element 4 - Document Evaluations and Submit Request**: Reviewers should ensure that the submittal includes sufficient information to support conclusions regarding the acceptability of the proposed change, and that the archival documentation of the evaluation process and findings is maintained and available for staff audit and review. Reviewers should also ensure that the licensee has requested the appropriate regulatory action (for example, a license amendment, an exemption, or a change to technical specifications). Where appropriate, reviewers should ensure that the submittal has documented any licensee proposed enhancements to regulatory requirements (e.g., high risk significant SSCs not currently subject to regulatory control may be subject to requirements commensurate with their risk significance). Finally, reviewers should ensure that LB changes are appropriately included in an updated safety analysis report, as necessary.

Application-Specific Reviews

This chapter of the SRP is intended to provide guidance for reviewing applications in risk-informed regulation where numerical values of risk indices play a relatively large role in the decisionmaking process and where a broad set of scenarios and plant operating modes may be affected. Where it is determined that an application could justify a review that is less than the full scope described in this document, reviewers should choose the relevant and applicable parts of this SRP chapter for guidance. The necessary sophistication of the review of the PRA, its supporting analyses, and its results depends on the contribution the risk assessment provides to the integrated decisionmaking. Application-specific SRP chapters (where available) provide additional guidance in this area.

II. ACCEPTANCE CRITERIA

This SRP chapter provides guidance for use in conducting staff reviews of PRA findings and risk insights in support of licensees' requests for changes to the LB of nuclear power plants (e.g., requests for license amendments under 10 CFR 50.90, and exemptions under 10 CFR 50.11). RG 1.174 sets forth guidance for licensees to use in implementing acceptable methods for conducting PRA and traditional engineering analyses to support such changes.

To evaluate licensee-initiated LB changes which are consistent with currently approved staff positions (e.g., regulatory guides, standard review plans, or branch technical positions), the staff normally uses traditional engineering analyses. Licensees generally would not be expected to submit risk information in support of such proposed changes. However, circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, even when all regulatory requirements are met. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety. The use of risk information in the review of such license amendment requests is addressed in Appendix D of this SRP chapter.

To evaluate licensee-initiated LB changes which go beyond current staff positions, the staff may use traditional engineering analyses as well as the risk-informed approach set forth in this SRP chapter. In such instances, licensees may be requested to submit supplemental risk information or traditional engineering information if such information is not already included as part of the original submittals. If risk information on the proposed LB changes is not provided, the staff will determine if the application can be approved on the basis of the information provided using traditional methods and will either approve or reject the application based upon this information. For those licensee-initiated LB changes which a licensee chooses (or is requested by the staff) to support with risk information, this SRP chapter describes the scope and content of the staff's review by considering engineering issues and applying risk insights.

Licensees submitting risk information to support changes to their LB (whether on their own initiative or at the request of the staff) should address each of the principles of risk-informed regulation discussed in RG 1.174. The staff should then determine if the licensees' selected approaches and methods (whether quantitative or qualitative, and traditional or probabilistic), data, and criteria for considering risk are appropriate for the decision to be made.

For each risk-informed application, reviewers should ensure that the proposed changes meet the following principles (Sections of this SRP chapter dealing with review guidance for each principle are identified in brackets):

1. The proposed change meets the current regulations unless it is explicitly related to a requested exemption or rule change, i.e., a "specific exemption" under 10 CFR 50.12 or a "petition for rulemaking" under 10 CFR 2.802. [Section III.2.1].

2. The proposed change is consistent with the defense-in-depth philosophy [Section III.2.1].

3. The proposed change maintains sufficient safety margins [Section III.2.1].

4. When proposed changes result in an increase in core damage frequency or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement [Sections III.2.2 and III.2.3].

5. The impact of the proposed change should be monitored using performance measurement strategies [Section III.3].

In demonstrating adherence to the above principles, reviewers should ensure that licensees address the following issues as part of their submittals:

- 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 desirable. For those cases when risk increases are proposed, the benefits should be described and should be commensurate with the proposed risk increases. The approach used to identify changes in requirements was used to identify areas where requirements should be increased as well as where they could be reduced [Section III.2.3].

- The scope, level of detail, and quality of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed LB change are appropriate for the nature and scope of the change and are based on the as-built and as-operated and maintained plant, including reflecting operating experience at the plant [Section III.2.2].

- ~~The portions of the plant-specific PRA relevant to the application should contain the characteristics and attributes of a PRA as defined in Appendix A to Regulatory Guide~~

~~1.174. It should also be subjected to an independent peer review to determine whether it contains those characteristics and attributes [Section III.2.2].~~

- The plant-specific PRA supporting the licensee's proposals has been subjected to quality controls such as an independent peer review or certification. [Section III.2.2].

- ~~The plant-specific PRA supporting the licensee's proposals has been subjected to quality assurance methods and quality control methods [Section III.2.2].~~

- Appropriate consideration of uncertainty is given in analyses and interpretation of findings, including using a program of monitoring, feedback and corrective action to address significant uncertainties [Sections III.2.2 and III.3].

- The use of core damage frequency (CDF) and large early release frequency (LERF) as bases for probabilistic risk assessment guidelines is an acceptable approach to addressing Principle 4. Use of the Commission's Safety Goal quantitative health objectives (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 [Section III.2.2].

- Increases in estimated CDF and LERF resulting from proposed LB changes will be limited to small increments. The cumulative effect of such changes should be tracked and considered in the decision process [Section III.2.2].

- The acceptability of the proposed changes should be evaluated by the licensee in an integrated fashion that ensures that all principles are met [Section III.2.3].

- Data, methods, and assessment criteria used to support regulatory decisionmaking must be well documented and available for public review [Section III.4].

III. REVIEW GUIDANCE AND PROCEDURES

For risk-informed applications, reviewers should ensure that licensees' submittals meet the principles specified in Section II of this SRP chapter, and address the expectations for risk-informed decisionmaking (also specified in Section II). This section provides guidance to assist reviewers in making this determination. For consistency, Sections III.1 through III.4 present this guidance in terms of the four elements of the approach described in Section 2 of RG 1.174.

III.1 Element 1: Define the Proposed Change

In this element, reviewers should verify that the submittal provides enough information to meet the staff's expectation that all potential safety impacts have been identified and evaluated. In addition, reviewers should be satisfied that, where appropriate, the licensee has identified design and operational aspects of the plant related to the change request that should be enhanced consistent with an improved understanding of their safety significance based on the methodology used to support the proposed relaxation in regulation. These enhancements should be appropriately reflected in changes to the plant's LB (e.g., technical specification, license conditions, and FSAR).

Reviewers must also assess the proposed changes as they relate to the plant's LB, which specifies how the licensee satisfies certain basic regulatory requirements such as diversity, redundancy, defense-in-depth, and the General Design Criteria. This assessment should include reviewing the engineering (or other pertinent) analysis and data that identify the safety margins, and plant design and/or activities conducted to preserve those margins. If exemptions from regulations or other forms of relief are needed to implement the licensee's proposed change, reviewers should ensure that the appropriate requests accompany the licensee's submittal.

Reviewers should also verify that the licensee has identified and appropriately used available information reflecting traditional engineering concepts and principles. Among the non-PRA sources of information that should be examined to support the evaluation of safety significance include the safety insights developed in licensing documents such as the FSAR, as well as the bases for the plant's Technical Specifications, which may include AOTs, limiting conditions for operation (LCOs), and surveillance requirements (SRs).

Where available, plant-specific data and operational information should be factored into the definition of the proposed change. Reviewers should consider the way in which the issues at hand are reflected in operational data. Useful insights from plant-specific operating experience can also be obtained from inspections that follow incidents at the facility, including incident investigation and augmented team inspections conducted by the NRC, incident assessments documented in significant operating event reports prepared by the Institute of Nuclear Power Operations (INPO), licensee follow-up investigations, and routine inspections by NRC resident inspectors. Inspection results can provide valuable qualitative insights in such areas as human performance, management controls, adequacy of procedures, and root causes of events, which are often difficult to treat with precision in a PRA.

Finally, as part of the initial review of the licensing amendment, reviewers should determine if the submittal adequately characterizes the impact of the proposed change (specifically, if the submittal identifies all SSCs or other plant elements affected by the proposed change) and if the analyses performed and submitted by the licensees have the scope and depth to adequately characterize the impact of the change.

Licensees may submit proposals which include several individual LB changes that have been evaluated and will be implemented in an integrated fashion. For example, individual changes may be grouped together for convenience (ease of implementation and/or review), or changes may be combined as risk tradeoffs (balancing risk increases with risk decreases). Changes grouped in this way should normally be related, for example by affecting the same single system or activity, the same safety function, or the same accident sequence group, or by being of the same type (e.g., changes in AOT). However, this does not preclude unrelated changes from being accepted. When combined change requests are submitted, the staff should conduct a detailed assessment of the relationship between the individual changes and how they have been modeled in the risk assessment. In its review, the staff should evaluate the acceptability of the individual changes and the overall impact of the combined changes with respect to the principles and expectations discussed in Section II of this SRP chapter. Section III.2.3 discusses the review of combined change requests in more detail.

III.2 Element 2: Conduct Engineering Evaluations

In order to make findings regarding the acceptability of a proposed license amendment, the staff should establish its position on the basis of an integrated assessment of traditional engineering evaluations and probabilistic information. Section 2.2 of Reg Guide RG 1.174 describes the specific evaluations that the licensee is expected to perform. The scope and quality of the engineering analyses conducted to justify a proposed change should be appropriate for the nature and scope of that change. Section 3 of RG 1.174 describes the various types of traditional engineering and probabilistic information which should be included in submittals.

The results of this element should be reviewed to determine if the submittal satisfies the following principles for risk-informed decisionmaking: the proposed change meets current regulations (unless the change is explicitly related to a requested exemption or rule change); the defense-in-depth philosophy is maintained; sufficient safety margins are maintained; and proposed increases in core damage frequency and/or risk (if any) are small and are consistent with the intent of the Commission's Safety Goal Policy Statement.

III.2.1 Evaluation of Defense-in-Depth Attributes and Safety Margins

Reviewers should assess the licensee's engineering evaluations to confirm that the principles identified in Section II are not compromised. These evaluations should include not only the traditional design basis accident (DBA) analyses, but also evaluations of the defense-in-depth attributes of the plant, safety margins, and risk assessments performed to obtain risk insights and to quantify the impact of the proposed change.

III.2.1.1 Defense-in-Depth

Defense-in-depth is defined as a philosophy which ensures that successive measures are incorporated into the design and operating practices for nuclear plants to compensate for potential failures in protection and safety measures. In risk-informed regulation, the intent is to ensure that the defense-in-depth philosophy is maintained, not to prevent changes in the way defense-in-depth is achieved. The defense-in-depth philosophy has been and continues to be an effective way to account for uncertainties in equipment and human performance. In some cases, risk analysis can help quantify the range of uncertainty; however, there will likely remain areas of large uncertainty or areas not covered by the risk analysis. Where a comprehensive risk analysis can be performed, it can help determine the approximate extent of defense-in-depth (e.g., balance among core damage prevention, containment failure, and consequence mitigation) to ensure protection of public health and safety. However, because PRAs do not reflect all aspects of defense-in-depth, appropriate traditional defense-in-depth considerations should also be used to account for uncertainties.

Preservation of Multiple Barriers for Radioactivity Release

Defense-in-depth can be evaluated on the basis of considerations involving the barriers that prevent or mitigate radioactivity release. Release of radioactive materials from the reactor to the environment is prevented by a succession of passive barriers including the fuel cladding, reactor coolant pressure boundary, and containment structure. These barriers, together with an imposed exclusion area and emergency preparedness, are the essential elements for accident consequence mitigation. Given these multiple barriers, safety is ensured through the application of deterministic safety criteria for the performance of each barrier, and through the design and operation of systems to support the functional performance of each barrier.

In maintaining consistency with the defense-in-depth philosophy, the proposed license amendment should not result in any substantial change in the effectiveness of the barriers. Consequently, reviewers should consider the following objectives to ensure that the proposed change maintains appropriate safety within the defense-in-depth philosophy:

- The change does not result in a significant increase in the existing challenges to the integrity of the barriers.

- The proposal does not significantly change the failure probability of any individual barrier.

- The proposal does not introduce new or additional failure dependencies among barriers that significantly increase the likelihood of failure compared to the existing conditions.

- The overall redundancy and diversity among the barriers is sufficient to ensure compatibility with the risk acceptance guidelines.

In demonstrating that the proposal fulfills the objectives listed above, the staff expects that the proposed change will meet the following guidelines:

- A reasonable balance is preserved among prevention of core damage, prevention of containment failure, and mitigation of consequences.

- The proposal avoids over-reliance on programmatic activities to compensate for weaknesses in plant design.

- The proposed change preserves system redundancy, independence, and diversity commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties.
- The proposal preserves defenses against potential common cause failures and assesses the potential introduction of new common cause failure mechanisms.

- The proposed change does not degrade the independence of barriers.

- The proposed change preserves defenses against human errors.

- The proposal fulfills the intent of the General Design Criteria in 10 CFR 50, Appendix A.

Reviewers can assess fulfillment of the above guidelines by using qualitative or traditional engineering arguments or by using PRA results contained in the accident sequences or cutsets.

Role of PRA in Review of Defense-in-Depth

In addition to the usual quantitative risk indices, PRAs provide important qualitative results, namely, the contributors to accident sequences. For PRAs that use the fault tree linking approach these contributors are described by the accident sequence minimal cutsets. Each accident sequence minimal cutset is a combination of passive and active SSC failures and human errors that would cause core damage or a release of radioactivity. The cutsets therefore directly show one particular aspect of defense-in-depth, in that they reveal how many failures must occur in order for core damage or radiological release to occur. Thus, the minimal cutsets show the effective redundancy and diversity of the plant design. For analysis approaches that use event trees with boundary conditions, the results take the form of accident sequence descriptions and typically include elements representing unavailabilities of systems (or trains of systems) rather than components. However, in most cases, cutsets providing a component level decomposition of the system (or train) unavailabilities are provided, and an equivalence to the minimal cutset description can be established if necessary.

In most cases, events appearing in each minimal cutset are targeted by programmatic activities to ensure the reliability of the associated SSC. Specific activities that are important to maintain the reliability of a component include: IST, ISI, periodic surveillance required by Technical Specifications, quality assurance, and maintenance. Therefore, when a review of the minimal cutsets reveals areas where redundancy or diversity are already marginal, it would arguably be inappropriate to reduce the level of activities aimed at ensuring SSC performance. (The exception would arise if the licensee can show that the activities have little or no effect on SSC performance, or if it can be shown that uncertainties in the performance of the elements in this cutset are well understood and quantified. It is also possible that the licensee could propose compensating or alternative activities to provide assurance of SSC performance.) The objective of this review is to avoid completely relaxing the defense-in-depth posture at points at which the plant design has the least overall functional independence, redundancy, and/or diversity. On the other hand, in areas where a plant has substantial redundancy and diversity, defense-in-depth arguments used to justify relaxations should be given appropriate weight.

As part of the defense-in-depth evaluation, reviewers should consider the effects of multiple component failures and common cause failures that could potentially result from the proposed change. For example, if the licensee proposes to reduce the requirements for all events in a cutset, reviewers should ensure that the effect of the change is properly modeled and that the change does not have an adverse effect on defense-in-depth.

Finally, in assessing the accident sequence cutsets, reviewers should devote attention to potential over-reliance on programmatic activities or operator actions that compensate for weaknesses in the plant design. For example, proposed maintenance and surveillance activities should complement and not replace proper plant design.

III.2.1.2 Safety Margins

In the determination of the design performance characteristics of a system, safety margin represents an allowance for uncertainty in SSC performance. Current safety analysis practices incorporate consideration of margin in most areas. As examples, many engineering standards, licensing analyses, and technical specifications take margin into account.

Incorporating margin can result in over-designing of components, incorporation of extra systems or system trains, or in conservative operating requirements for systems and components. Therefore, some licensee applications will seek to reduce this margin in some areas. Such reductions should appropriately reflect the current understanding of existing uncertainties and the potential impact of the proposed change. Therefore, in evaluating a proposed change request, reviewers should establish that the proposal fulfills the following guidelines:

- The proposal meets established engineering codes and standards or NRC-approved alternatives, or deviations are justified.

- The proposal meets the safety analysis acceptance criteria in the LB, or proposed revisions provide sufficient margin to account for uncertainty in the analysis and data.

Clearly, these guidelines are closely related to the guidance provided in Section III.2.1.3 regarding the need to maintain the LB. The thrust of the guidance in the present section is to sensitize reviewers to the implications of relaxing the margin when evaluating the acceptability of changes to the LB.

The level of justification required for changes in margin should depend on how much uncertainty is associated with the performance parameter in question, the availability of alternatives to compensate for adverse performance, and the consequences of functional failure of the affected elements. Therefore, the results derived from risk evaluations and the associated analysis of uncertainties (especially in the analysis areas and models affected by the application) will provide useful information to help in the reviewers' decisionmaking. As an example, in evaluating available safety margins, reviewers should consider the risk profile of the plant. If a proposed LB change creates or exacerbates a situation where risk is dominated by a few elements (SSCs or human actions) or a few accident sequences, the reviewers should carefully evaluate the modeling of these elements or sequences including the modeling of uncertainties. Reviewers should consider the results from the analysis of uncertainty when determining of the acceptability of the reduction in margin from the proposed change.

In demonstrating available safety margins, licensees will, in some cases support their proposal by citing new data from plant tests or research projects, or will conduct analyses using models that are predicated on new data. The following examples illustrate situations in which data and analyses can be used effectively to support the LB change request:

- It is shown that a phenomenon of concern cannot occur or is less likely to occur than originally thought.

- It is shown that the amount of safety margin in the design is significantly greater than that which was assumed when the requirement or position was imposed.

- It is shown that time available for operator actions is greater than originally assumed.

The reviewers' primary objective is to verify the relevance and acceptability of the new information with respect to the requested LB change. Data that directly apply to the original technical concern should be considered in the decision process. Depending on the circumstances, the cognizant review branch may have additional specific guidance available for use in reviewing the quality and acceptability of the data. However, the data or analyses must be clearly applicable to the plant and specific circumstances in which they are being applied.

III.2.1.3 Current Regulations

Reviewers should ensure that the proposed change satisfies current regulations (including the General Design Criteria), unless the licensee explicitly includes a proposed exemption or rule change (i.e., a "specific exemption" as allowed by 10 CFR 50.12 or a "petition for rulemaking" in accordance with 10 CFR 2.802).

The LB also applies until the staff approves modifications to the existing basis. It is expected that some applications will seek to modify the LB in risk-informed submittals. Applications that seek to make qualitative changes to the LB (such as moving components out of the scope of a required program) should be reviewed in greater detail with respect to defense-in-depth and safety margins when compared to applications that seek to make parametric changes (such as incremental changes to surveillance interval).

III.2.2 <u>Risk Assessment</u>

For effective implementation of risk-informed regulatory approaches, reviewers should ensure that the licensee has demonstrated that the plant's design and actual operating conditions and practices are properly reflected in the risk insights derived using the plant-specific PRA model. Otherwise, the risk assessment may provide inaccurate or misleading information that will require careful scrutiny before use in any regulatory decisionmaking process.

Development of a plant-specific, risk-informed program also requires the availability of information to identify the SSCs and human actions that contribute most significantly to the plant's estimated risk. In addition, it is necessary to be able to capture the impact of the proposed change on the elements of the PRA. Section III.2.2.1 of this SRP chapter discusses the characterization of the proposed change in terms of PRA model elements. The results of this determination of the cause-effect relationships between the proposed application and the PRA models will help define the scope and level of detail required for the PRA to support the application. Sections III.2.2.2 and III.2.2.3 discuss these topics.

Many applications, such as those involving changes in component test intervals, allow explicit PRA modeling of the impact of the proposed change and quantification of the expected change in risk using plausible models of the impact on SSC unavailability to the extent that the affected components are included in the plant's PRA. For other risk-informed applications, however, it may not be feasible to explicitly model the cause-and-effect relationship because the resulting actual impact on component unavailability is not clearly understood. For such applications, the use of risk categorization techniques provides a useful way to identify groups of SSCs that are less risk important to risk and, as such, are possible candidates for a graded approach to regulatory requirements. Using such a categorization approach, however, it is still necessary to understand the potential or bounding impact of the proposed change, and to assess the risk impact through appropriate sensitivity studies. In either the detailed quantification approach or the risk categorization approach, risk results should be derived from analyses of appropriate quality. Section III.2.2.4 and Appendix A to this SRP chapter present guidelines to help reviewers evaluate PRA quality as a function of the application. Finally, Appendix C to this SRP chapter discusses review issues related to the determination of risk contribution and component categorization.

III.2.2.1 Characterization of Change in Terms of PRA Model Elements

Where quantitative PRA results are used as part of a risk-informed evaluation of a proposed change, the licensee should define the change in terms that are compatible with the risk analysis, i.e., the risk analysis should be able to effectively evaluate the effects of the change.

The approach to risk characterization should establish a cause-effect relationship to identify portions of the PRA affected by the issue being evaluated. This includes (i) identifying the specific PRA contributors for the particular application, (ii) assessing the portions of the model that should be modified for the application, and (iii) identifying supplemental analyses that could be used to support the application. This approach will help reviewers determine the scope and level of detail of analysis required for the remaining steps in the change process.

Table III-1 of this SRP chapter summarizes the general guidance for use in identifying elements of the PRA model that may be affected by an application. This guidance, presented as a list of questions, will assist reviewers in establishing a cause-effect relationship between the application and the PRA model. The answers to these questions should be used to identify the extent to which the proposed change affects the design, operation, and maintenance of plant SSCs.

Reviewers should also verify that the effects of the proposed changes on plant elements (SSCs, operator actions, etc.) are adequately characterized in the elements of the PRA model, or by appropriate changes to the logic model structure. For full-scale applications of the PRA, for example, this should be reflected in a quantification of the impact on the PRA results. For applications like component categorization, however, sensitivity studies on the effects of the change may be sufficient. Similarly, for other applications, it may be adequate to define the qualitative relationship of the impact on the PRA elements, or it may simply be necessary to identify of which elements are impacted.

The review procedure for this element is therefore intended to verify that the submittal appropriately accounts for the effects of the changes on SSC reliability and unavailability, or on operator actions. Where applicable, reviewers should also evaluate the modeling and quantification of the effects of the change ensure that the models are appropriate and that the results can be supported by plant and/or industry data.

III.2.2.2 Scope of Analysis

The necessary scope of a PRA supporting risk-informed requests will depend on the specific application. Although the assessment of risk implications (in light of the acceptance guidelines defined in RG 1.174) requires that all plant operating modes and initiating events be addressed, it is not necessary in risk-informed regulation that licensees submit PRAs that treat all plant operating modes and all initiating events. Instead, when full-scope PRAs are not available, reviewers should ensure that the submitted findings are supportable on the basis of traditional engineering analyses or other plant operational information addressing modes and initiators not analyzed in the base PRA.

For plant modes and initiators not analyzed in the PRA (such as shutdown, seismic events, fire, floods and severe weather), the licensee should consider the effects of the change and provide the rationale for why additional PRA analyses are not necessary. This rationale could be addressed by assessing the level of redundancy and diversity provided by the plant systems, system trains, human actions, etc. for responding to these unanalyzed initiating events. The licensee should also show that the proposed change does not introduce unanalyzed vulnerabilities and that redundancy and diversity will still exist in the plant response capability after the changes are implemented. This issue is addressed acceptably if the proposal fulfills any one of the following criteria:

- The licensee addresses all modes and all initiator types using PRA.

- The licensee demonstrates that the application does not unacceptably degrade plant capability and does not introduce risk vulnerabilities or remove elements of the plant response capability from programmatic activities aimed at ensuring satisfactory safety performance for plant modes and initiator types not included in the PRA.

- If the proposed change impacts unanalyzed plant modes or initiator types, the licensee demonstrates that a bounding analysis of the change in plant risk from the application (e.g., by qualitative arguments, or by use of sensitivity studies) meets guidelines that are equivalent to the acceptance guidelines specified in Section 2.2.4 of RG 1.174.

III.2.2.3 Level of Detail

The level of detail in a PRA required to support an application should be such that the proposed changes to the plant can be adequately characterized in the PRA model elements, as discussed in Section III.2.2.1 of this SRP chapter. In addition, the PRA should be detailed enough to account for important system and operator dependencies (functional, operational, and procedural) especially for those components affected by the application. A review of the licensee's failure modes and effects analysis and a review of plant operating and emergency procedures will be useful for this purpose.

The usefulness of PRA results in risk-informed regulation is dependent on the level of resolution of the modeled SSCs. A component-level resolution provides insights at the component level. However, if a PRA is performed at a system or train level, the insights of the PRA will be limited to that level unless it can be demonstrated that component-level insights can be bounded by, or deduced from, system- or train-level effects. The direct application of PRA results will therefore be limited to those SSCs that are explicitly modeled as part of the PRA basic events. Insights for SSCs that are implicitly modeled (i.e., screened out, assumed not important, etc.) shall only be used after additional consideration of the effects of the proposed change on PRA assumptions, screening analyses, and boundary conditions.

Specifically, the following relationships exist between the level of detail in the modeling of each SSC and the conclusions that can be drawn from the PRA:

- If the SSCs are modeled at the basic event level, i.e., each SSC is represented by a basic event (or sometimes, more than one if different failure modes are modeled), risk insights from the PRA can be applied directly to the modeled component as long as the effects of the change are appropriately considered.

- If the SSCs are included within the boundaries of other components (e.g., the governor and throttle valves being included in the pump boundary), or if they are included in "black boxes" or modules within the PRA model, or if they are modeled as part of the calculation of human error probabilities (HEPs) in recovery actions, risk insights from the PRA can be applied if the effects of the application can be mapped onto the events (e.g., modules, HEPs, etc.) in question. In these cases it should be noted that the mapping is relatively simple if the event is under the same "OR gate" with the other module or HEP events. However, if the logic involves "AND gates," the mapping is more complicated.

- If the SSCs are omitted from the model because of inherent reliability, or if they are not modeled at all, risk insights for these components should be obtained through an integrated decisionmaking process (such as an Expert Panel) that revisits the assumptions or screening criteria used to support the initial omission.

III.2.2.4 Quality of a PRA for Use in Risk-Informed Regulation

The baseline risk profile is used to model the plant's licensing basis and operating practices that are important to safe operation. As such, the profile may provide insights into areas in which existing requirements can be relaxed without unacceptable safety consequences. It is therefore essential that the PRA adequately represent the risk profile. To complement this requirement, it is necessary to identify those elements of the plant that are responsible for reducing the risk to acceptable levels, and to adequately address those elements in the licensee's programmatic activities. Therefore, the following criteria should be satisfied in risk-informed regulation.

- A reasonable assurance exists with regard to the adequacy of the PRA. That is, the PRA model properly reflects the actual design, construction, operating practices, and operating experience of the plant and its owner. This should include plant changes due to the licensee's voluntary actions, regulatory requirements, or previous changes made to the LB.

- The results and conclusions are "robust" and, where appropriate, the licensee has conducted an analysis of uncertainties and sensitivities to show this robustness.

- Key performance elements are appropriately classified, and performance is backed up by licensee actions. PRA results are dependent on plant activities. They reflect not only inherent device characteristics, but also numerous programmatic activities, such as IST, ISI, quality assurance, maintenance, etc. Use of a PRA to justify relaxation of a requirement should therefore imply a commitment to the important programmatic activities that are needed to maintain performance at the PRA-credited levels that served as the basis for the proposed relaxation.

Review of the PRA Quality Required for an Application

The submittal must demonstrate that the licensee's technical analysis is of an appropriate quality. The required PRA quality should be commensurate with the application for which it is applied and the role the PRA results play in the integrated decisionmaking process. The more emphasis that is placed on the risk insights and PRA results in the decisionmaking process, the more requirements have to be placed on the PRA in terms of how well the licensee assesses the risk and/or the change in risk. Emphasis on the PRA review may be reduced if a proposed change to the LB decreases the risk or is risk neutral, or if proposed risk increases are calculated to be very small, or if the decision could be based largely on traditional engineering arguments, or if the licensee proposes compensating measures and/or qualitative factors (such as unquantified benefits) such that it can be convincingly argued that the change improves safety or the risk increase is very small.

In assessing the acceptability of a PRA for an application, reviewers should evaluate the licensee's process to ensure quality. In addition, reviewers should reach specific findings regarding the quality of the PRA for each application. At a minimum, reviewers should reach these findings on the basis of a "focused-scope" evaluation that concentrates on application specific attributes of the PRA and on the assumptions and elements of the PRA model that drive the results and conclusions. Appendix A to this SRP chapter provides more detailed guidance regarding several issues that are important to the application-specific reviews of probabilistic evaluations performed as part of risk-informed regulation.

The robustness of the results can be determined by developing an understanding of the contributors and the sources of uncertainty that impact the results. For the proposed risk change, reviewers should identify the elements that increase risk and those that decrease risk, and then identify the contributors to both the risk increase and decrease. A review of the basic events, assumptions, and uncertainties involved in the increase and decrease in risk will help reviewers understand the elements that are important in determining the risk change, and thus ensure that the conclusions are robust with respect to the results obtained.

In addition to the focused-scope review, reviewers should consider the following factors in determining the need for a more detailed and larger scope staff review of the PRA:

- The PRA results play a relatively significant role in the decisionmaking process, coupled with the finding that the proposed change in risk and/or the baseline risk is close to the decision guidelines as defined in Section 2.2.4 of RG 1.174.

- Staff audits of the licensee's process for conducting a PRA have identified practices that could detrimentally affect the quality of the technical analysis.

- Results of the licensee's analysis submitted in support of a licensing action are in some way counter-intuitive or inconsistent with results for similar plants on similar issues.

- The licensee's analysis is part of a pilot application of PRA in a regulatory activity.

- The PRA includes new methods that are unfamiliar to the staff.

When a staff review of the base PRA is necessary, reviewers should begin by evaluating the results and conclusions from available independent peer reviews of the PRA.[2] The staff review should take into account the process used in the peer review (including the review guidelines or standards to which the PRA is compared, the review scope and elements, the qualification and makeup of the review team, etc.). Results from previous staff reviews of the PRA (e.g., from previous applications) could also provide a good starting point. In cases where the PRA is based on the individual plant examination (IPE) or the IPE of externally initiated events (IPEEE) models, reviewers should also be familiar with the request for additional information (RAI) issued by the staff in connection with those examinations, as well as the licensee's responses to those RAIs, and the staff evaluation reports regarding the licensee's IPE and IPEEE submittals.

Reviewers could reach a finding that previous industry or staff reviews are sufficient to show that the PRA is of adequate quality in one or more of the review areas for the present application. In such cases, the scope of the review should be adjusted accordingly. However, reviewers should be aware of potential application-specific differences, and of the currency of the previous review findings with respect to the current plant design and operating procedures.

It should be noted that the NRC has not developed its own formal standards nor has it yet endorsed an industry standard for PRAs submitted in support of applications for changes to a plant's LB that are covered by this Standard Review Plan chapter. However, the NRC continues to support ongoing initiatives to develop such standards and expects that ultimately PRA standards will be developed and endorsed by the NRC that are suitable for regulatory decisionmaking as described in this Standard Review Plan chapter. Currently under development are standards for internal events, external events (e.g., seismic, high winds and external flooding), and low power and shutdown modes of operation.[3]

Quality Assurance Requirements Related to the PRA

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[2] In April 2000, the Nuclear Energy Institute submitted a process (Ref. 7) for peer review of licensee PRAs. It was submitted for staff review in the context of its use in categorizing SSCs with respect to special treatment requirements (i.e., supporting NRC's risk-informed "Option 2" work (SECY-99-256, Ref. 8)). This process may also be of use in LB changes (as well as other regulatory activities not addressed here); if so, future revisions of this Standard Review Plan chapter may endorse this certification process for this purpose.

[3] The American Society of Mechanical Engineers (ASME) is developing a draft standard, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications." ~~Revision 12 of this standard was issued for public comment in May 2000.~~ It is expected by spring 2002. This standard is for level 1 and level 2 (LERF only) PRAs for internal events (excluding fire) that occur during full power operations.

The American Nuclear Society (ANS) is developing a draft standard for external events (e.g., seismic, including seismic margins, wind, flood), "External Events PRA Methodology Standard." A draft was issued for public comment in January 2001. The ANS is also developing a draft standard for low power and shutdown conditions, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications: Low Power and Shutdown," which is scheduled for issuance for public comment in December 2002. In addition, the various engineering professional societies are considering developing a Standard for performing a fire PRA.

To the extent that a licensee elects to use PRA as an element to enhance or modify its implementation of activities affecting the safety-related functions of SSCs, appropriate quality requirements will also apply to the PRA. In this context, therefore, a licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis. Section 2.5 of RG 1.174 describes the quality elements that apply to the licensee's PRA activities. Reviewers should verify that the quality of analyses and performance programs which affect safety-related equipment and activities will meet the quality guidelines described in RG 1.174.

III.2.2.5 Evaluation of Risk Impact

In evaluating the risk impact from an application, reviewers should consider the proposed change in risk with regard to the acceptance guidelines, the cumulative and synergistic effects of the application on the overall plant risk profile, and the licensee's risk management philosophy. Each of these items is discussed in the following subsections.

Acceptance Guidelines for Risk Impact from the Application

For many risk-informed applications, the licensee is expected to perform a quantitative estimate of the total impact of a proposed action to demonstrate that Principle 4 (see Section II) has been satisfied. Section 2.2.4 of RG 1.174 discusses the acceptance guidelines for changes to the plant's risk. To summarize, regions are established in the two planes generated by a measure of the baseline risk metrics (CDF and LERF) along the x-axis, and the change in those metrics (ΔCDF and ΔLERF) along the y-axis (Figures III-1 and III-2), and acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full-scope assessment (including internal events, external events, and events that take place under full power, low power and shutdown conditions). However, reviewers should recognize that many PRAs are not full-scope assessments and the use of less than full-scope PRA information may be acceptable as discussed later.

There are two acceptance guidelines, one for CDF and one for LERF, and both should be used. The guidelines for CDF are as follows:

- If the application can clearly be shown to decrease CDF, the change is considered to satisfy the relevant principle of risk-informed regulation with respect to CDF. (Because Figure III-1 is drawn on a log scale, it does not explicitly indicate this region.)

- When the calculated increase in CDF is very small (less than 1×10^{-6} per reactor year), the change should be considered regardless of whether there is an assessment of total CDF (Region III). While there is no requirement for the licensee to quantitatively assess the total CDF, information should be provided to show that there is no indication that the total CDF could considerably exceed 1×10^{-4} per reactor year. Such an indication could result, for example if the contribution to CDF calculated from a limited-scope analysis (such as that from the IPE or the IPEEE) significantly exceeds 1×10^{-4} per reactor year, if the licensee has identified a potential vulnerability from a margins-type analysis, or if plant operating experience has indicated a potential safety concern.

- When the calculated increase in CDF is in the range of 1×10^{-6} to 1×10^{-5} per reactor year, applications should be considered only if the licensee can reasonably show that the total CDF is less than 1×10^{-4} per reactor year (Region II).

- Applications which increase CDF by more than 1 x 10^{-5} per reactor year (Region I) should not normally be considered.

The CDF-related guidelines listed above are to be applied together with the guidelines for LERF. That is, both sets of guidelines should be satisfied. Specifically, the guidelines for LERF are as follows:

- If the application can clearly be shown to decrease LERF, the change is considered to satisfy the relevant principle of risk-informed regulation with respect to LERF. (Because Figure III-2 is drawn on a log scale, it does not explicitly indicate this region.)

- When the calculated increase in LERF is very small (less than 1 x 10^{-7} per reactor year), the change should be considered regardless of whether there is an assessment of total LERF (Region III). While there is no requirement for the licensee to quantitatively assess the total LERF, information should be provided to show that there is no indication that the total LERF could considerably exceed 1 x 10^{-5} per reactor year. Such an indication could result, for example, if the contribution to LERF calculated from a limited scope analysis (such as that from the IPE or the IPEEE) significantly exceeds 1 x 10^{-5} per reactor year, if the licensee has identified a potential vulnerability from a margins-type analysis, or if plant operating experience has indicated a potential safety concern.

- When the calculated increase in LERF is in the range of 1 x 10^{-7} to 1 x 10^{-6} per reactor year, applications should be considered only if the licensee can reasonably show that the total LERF is less than 1 x 10^{-5} per reactor year (Region II).

- Applications which increase LERF by more than 1 x 10^{-6} per reactor year (Region I) should 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.

The guidelines discussed above are applicable for full-power, low-power, and shutdown operations. However, during certain shutdown operations when the containment function is not maintained, the LERF guidelines as defined above are not practical. In such cases, the licensee 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.

~~The risk analyses from which the above LERF guidelines were derived are based on UO_2-fueled cores operating at power levels up to 3,800 Mwt and fuel burnups of up to approximately 40,000 MWD/MT. Small increases in power level to a resultant power level no more than 3,800Mwt, are not expected to have an appreciable effect on the current LERF guideline. However, power level increases resulting in levels above 3,800 Mwt may need to be evaluated for their impact on these LERF guidelines.~~

~~Changes in fuel burnup are also not expected to have any appreciable effect on the above LERF guideline since early fatality risks are dominated by the short lived fission products, while high burnup primarily affects the long-lived fission products. However, to better understand these issues, the NRC is convening a study to identify and to determine importance of the phenomena related to high burnup and mixed oxide (MOX) fuels. This study is expected to be published for~~

~~public comment in June 2001. The NRC staff will use the results to establish the basis for changes (if any) to the current LERF guidelines.~~

As indicated by the shading in Figures III-1 and III-2, the change request should be subjected to technical and management reviews which become more intensive as the calculated results approach the region boundaries. The technical review related to the risk evaluation should address the scope, quality, and robustness of the analysis, including consideration of uncertainties. The scope, level of detail, and quality of analysis is further discussed in Sections III.2.2.2, III.2.2.3, and III.2.2.4 of this SRP chapter. The robustness of the results can be determined by developing an understanding of the contributors, the sources of uncertainty that impact the results, and their impact on whether the acceptance guidelines are met.

The necessary sophistication of this evaluation depends on both the role the risk assessment plays in the decision and the magnitude of the potential risk impact. For those actions justified primarily by traditional engineering considerations and for which minimal risk impact is anticipated, a bounding estimate may be sufficient. For actions justified primarily by PRA considerations for which a substantial impact is possible or is to be offset with compensatory measures, an in-depth and comprehensive PRA analysis is generally needed.

Comparison of Results with Acceptance Guidelines

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 III-1 and III-2 are approximate values used to indicate the changes that are generally acceptable. Furthermore, the state of knowledge (or epistemic) uncertainties associated with PRA calculations preclude a definitive decision (based purely on the numerical results) with respect to which region a given application belongs. The intent in making the comparison of the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that the proposal fulfills Principle 4 (discussed in Section II). The assessment of whether this has been demonstrated must be made on the basis of an understanding of the contributors to the PRA results, and on 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; therefore, in order to complete the assessment, reviewers must carefully document the reasoning behind the decisions.

As discussed in RG 1.174, PRA values can be affected by particular modeling assumptions that are a response to the uncertainty regarding how to correctly model the plant response following an initiating event. Thus, it is important that uncertainties in the PRA results be taken into account in assessing the risk impact and in the risk-informed decisionmaking process to demonstrate the robustness of the results. The scope of the required uncertainty analysis is a function of the role that the quantification results play in the decision, and on the significance of the calculated change.

The general approach to accounting for uncertainty is discussed in Section 2.2.5 of RG 1.174. In that discussion, uncertainties are categorized as parameter, model, and completeness uncertainties. In assessing analysis of uncertainties, reviewers should consider the types and sources of uncertainties identified by the licensee, and how those uncertainties have been addressed with reference to the decision guidelines. Specifically, review guidance is as follows.

- Parameter uncertainty: Reviewers should determine whether the licensee has accounted for parameter uncertainties in an appropriate manner so that the estimated values for $\triangle$CDF, $\triangle$LERF, CDF, and LERF can be regarded as equivalent to mean values. However, this does not imply that a detailed propagation of uncertainties is always necessary; in many cases, it is possible to show that a point estimate is an acceptable approximation of the mean value using qualitative arguments about the risk contributors. For example, if a formal propagation has not been performed, it is necessary for the licensee to demonstrate that the result is not affected by the so-called state of knowledge correlation (specifically, that there are no significant contributing cutsets or scenarios that involve multiple events for which the probabilities are determined using the same parameter, particularly if the parameter value is very uncertain).

  It is not uncommon for licensees to use point estimate values without defining probability distributions on the values. In such instances, it is not possible to characterize the point estimate as a mean value. However, for the more significant parameters, some characterization of uncertainty is essential to demonstrate that the point estimate is not an optimistic value.

- Model uncertainty: Reviewers should determine if the results are strongly impacted by the specific models or assumptions adopted for the assessment of important elements of the PRA, and whether the sensitivity analyses that have been performed (if any) are sufficient to address the most significant uncertainties with respect to these elements.

  In some cases, particularly for small changes in risk or for relatively minor changes, there may be relatively few issues related to model uncertainties. In other cases, where the baseline risk values are to be estimated, the modeling issues should include all those that have a significant impact on the evaluation of the baseline risk values. Model uncertainties arise when there are several alternative approaches to the analysis of certain elements of the PRA model. They are typically addressed by adopting a specific model or making a specific assumption. In such cases, the licensee should document why the particular model or assumption used is appropriate both for the base case risk evaluation and for the analysis of the impact of the change. In certain cases, it may be necessary to perform sensitivity analyses using alternative reasonable models or assumptions to demonstrate the robustness of the conclusions. In deciding what are reasonable alternatives, reviewers should consider whether the alternatives have some precedent and whether they have a reasonable engineering basis.

  Reviewers should pay particular attention when the characterization of a model uncertainty is such that the results fall into a bimodal or multi-modal distribution, and one or more of the modes exceed the acceptance guidelines. The results should then be reviewed on the basis of an evaluation of the significance of the hypotheses associated with those modes that exceed the guidelines.

- Completeness uncertainty: Reviewers should determine whether the licensee has adequately addressed the limitations in the PRA scope, and other completeness issues either by limiting the scope of the application, or by demonstrating that the impact of the unanalyzed portion of the risk on both the base case risk and on the change in risk is bounded or can be neglected. Section III.2.2.2 of this SRP chapter discusses this further.

Cumulative and Synergistic Effects from all Applications

In evaluating the licensee's submittal, reviewers should consider the effects of the proposed changes in light of previously submitted changes implemented by the licensee. Optimally, the PRA used for the current application should already model the effects of past applications. However, qualitative and synergistic effects are sometimes difficult to model in the PRA. Therefore, a review of changes in risk (both quantifiable and non-quantifiable) from previously submitted changes to the plant's design and operation would provide a means to account for the cumulative and synergistic effects of these changes.

For all previous changes, reviewers should consider the following factors:

- the calculated change in risk for each application (CDF and LERF) and the plant elements (SSCs, procedures, etc.) affected by each change

- qualitative arguments used to justify the change (if any) and the plant elements affected by those arguments

- compensatory measures or other commitments used to help justify the change (if any) and the plant elements affected

- a summary of the results from the monitoring programs (where applicable) and a discussion on how these results have been factored into the PRA or into the current application

- the plant risk profile to ensure that the accumulation of changes has not created dominant risk contributors

If the licensee's submittal includes past changes made to the plant (but not submitted to the NRC) that reduced the plant risk, especially changes related to the current application, reviewers should consider such changes in the integrated decisionmaking process. Benefits from the implementation of the Maintenance Rule can also be credited for the applicable SSCs.

Beyond cumulative effects, synergistic effects are also possible, and some of these might not emerge from a quantification of the PRA. For example, if conventional importance ranking approaches are employed to determine the importance of SSCs, it would be possible that multiple requirements could be relaxed on certain "low" significant components under multiple applications. If the QA (potentially affecting the failure rate) and the test interval (potentially affecting fault exposure time) were to be relaxed for the same component, the component unavailability could increase more than expected (since failure rate and fault exposure time combine multiplicatively in the calculation of unavailability). If the effects of QA on failure rate could be quantified convincingly, this would be addressed explicitly, but this cannot presently be ensured. As a result, potential exists that different applications might lead to unintended and unquantified synergistic effects on the unavailability of a given component.

Synergistic effects on a given element can be addressed by showing that the basic event model adequately reflects the effects of programmatic activities, and that the calculated unavailability, propagated through the PRA, is consistent with the needed performance with regard to the risk indices and the defense-in-depth concept. However, it is more straightforward simply not to allow for the relaxation of multiple programmatic requirements on a given component, unless demonstrable justification is provided that the risk contribution from the component is negligible for conditions covered by the set of requirements. For example, if IST is relaxed on a given component, it would be preferable not to relax QA as well, unless good arguments are given for allowing both.

Risk Management

One of the goals of the review should be to ensure that in the course of the licensee's engineering evaluations, principles of risk management are appropriately applied in the process of evaluating changes to current regulatory requirements. For the purposes of this SRP chapter, "risk management" refers to an approach to decisionmaking about safety that seeks to allocate available resources and worker dose in such a way as to minimize the risk to public health and safety from plant operations. The staff should recognize that there is a point of diminishing returns in risk reduction and that some residual risk will be associated with plant operation. Nonetheless, reviewers should expect that licensees will make an effort to identify reasonable and cost-effective measures to control this residual risk as part of the risk-informed regulatory process.

Therefore, as a staff expectation, the process of risk management in risk-informed decisionmaking should not be biased toward eliminating requirements to the exclusion of enhancements that would convey a worthwhile safety benefit. Licensees are expected to apply risk insights in an unbiased way, and licensees who do not satisfy subsidiary safety objectives (as defined in RG 1.174) are expected to seek safety enhancements in conjunction with risk-informed applications.

Therefore, when risk increases are proposed, reviewers should consider plant performance and past changes to the licensing basis to ensure that there is no pattern for a systematic increase in risk. Insights on the licensee's operational practices, management controls, risk management programs, plant configuration control programs, or performance monitoring programs from previous applications can be obtained from the NRC project managers, the NRC regional offices, or documentation of NRC inspection activities.

III.2.3 <u>Integrated Decisionmaking Process</u>

The acceptability of the proposed changes should be reviewed and determined in an integrated fashion. Staff reviewers should verify that the licensee has used the results of the traditional engineering analyses and the risk assessment to ensure that the submittal fulfills the principles listed in Section II of this SRP chapter. Since the roles played by the traditional analyses and the risk analyses in the decisionmaking process determine the scope, quality, and robustness required of those analyses, examination of the appropriate inputs and assumptions in the analyses may be necessary for reviewers to conclude with reasonable assurance that the proposal fulfills the stated principles.

When appropriate, the integrated decisionmaking process should include implementation and monitoring strategies that are used to provide confidence that the results of the underlying engineering analyses remain valid. In addition, licensees can take compensatory measures which reduce risk to offset incompleteness or uncertainties in the analysis. Compensatory measures can also be used to offset a quantifiable increase in risk with non-quantifiable but expected improvements in safety.

In addition, the reviewer should ensure that the scope of the proposed changes is commensurate with, and fully supported by, the results of the analyses. That is, the scope of the change should be dependent on the degree of completeness of, level of detail of, and confidence in, the analyses. As an example, if the application concerned changing the treatment of SSCs according to their safety significance, a more detailed PRA model would allow a more detailed categorization into high or low significance than would a less detailed PRA model. Consequently, it would be expected that more SSCs could be characterized as low safety significant in the former case than the latter. It should be noted that both PRAs in this example may be stated to have sufficient quality for supporting the results as they were used in the decision. In this sense, quality can be thought of as a measure of the confidence in the results.

To ensure that the important assumptions used in the engineering analysis to justify the LB change remain valid, the integrated decisionmaking process should ensure that the licensee maintains an appropriate set of programmatic activities (e.g., IST, QA, ISI, maintenance, monitoring) for important elements of the plant response capability. In addition, performance of compensating SSCs should be ensured (through programmatic activities) when these SSCs are used to help justify the relaxation of requirements for other SSCs.

The process used by licensees to integrate traditional and probabilistic engineering evaluations for risk-informed decisionmaking is expected to be well-defined, systematic, and scrutable. Appendix B to this SRP chapter presents review guidance and staff expectations for the licensee's integrated decisionmaking process.

In evaluating the acceptability of a proposed change, reviewers should also address the following factors:

- the cumulative impact of previous changes and the trend in CDF and 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, including for example, siting factors, inspection findings, performance indicators, operational events, and Level 3 PRA information if available
- the benefit of the change in relation to its CDF/LERF increase, and whether it is practical to accomplish the change with a smaller CDF/LERF impact
- practical actions that could reduce 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)

Review of Combined Change Requests

In assessing combined change requests, reviewers should evaluate the acceptability of each of the individual changes with respect to the defense-in-depth and safety margin guidelines discussed in Section III.2.1 of this SRP chapter. In addition, reviewers should evaluate the overall risk impact of the combined changes using the guidelines discussed in Section III.2.2 of this SRP chapter.

In evaluating the overall (i.e., combined) risk impact, reviewers should take into account the relationship between the individual changes. For example, in combined change requests for which individual changes that increase risk are compensated for by other changes that decrease risk, reviewers should evaluate and understand the major contributors to both the risk increase and risk decrease, including the analysis assumptions and uncertainties from each contributor that might affect the decision process. Combining risk impacts from the individual contributors is prudent when the contributors are closely related in terms of analysis assumptions and uncertainty. Contributors could also be related if they impact on the same plant functions, for example. Conversely, for contributors that are not closely related, risk impacts from each change should be evaluated on an individual basis.

Finally, combined changes should not trade many small risk decreases for a large risk increase (i.e., create a new significant contributor to risk). It is expected that implementation of combined change requests will improve, or at least maintain, the overall plant risk profile. A desirable risk profile is one in which no contributors are overly dominant. Therefore, proposed changes should not create or exacerbate a risk imbalance either in terms of dominant plant elements (SSCs or operator actions) or accident sequences.

III.3 Element 3: Develop Implementation and Monitoring Strategies

Implementation and monitoring strategies are important in most risk-informed processes since they can provide an early indication of unanticipated degradation of SSCs or other plant performance factors under the proposed changes. In addition, these strategies may be needed to ensure that the plant will effectively maintain the performance of SSCs that are relied upon to justify the proposed change to the LB. Section 2.3 of RG 1.174 provides guidance for the suggested process related to this issue.

The primary goal of the monitoring program should be to ensure that no adverse degradation occurs because of the changes to the LB. These programs should therefore address the possibility that the aggregate impact of changes which affect a large class of SSCs could lead to an unacceptable increase in the number of failures attributable to unanticipated degradation, including possible increases in common cause failure mechanisms.

Reviewers should evaluate the implementation and monitoring strategies on the basis of findings obtained from the traditional engineering and probabilistic evaluations. When broad implementation is proposed over a short period of time, reviewers should verify that this is consistent with the traditional engineering evaluations, defense-in-depth considerations (including common cause failure), and risk evaluation models and assumptions. When there is a need to gain additional performance insights given a change in requirements, reviewers should verify that the licensee has proposed a phased approach to implementation. If this phased approach involves plan implementation for different SSC groups at different times, reviewers should also assess the basis for the licensee's grouping criteria, keeping in mind the potential common cause failures.

Monitoring should be applied to SSCs in a manner commensurate with their importance to safety as determined by the engineering evaluation that supports the LB change. This monitoring should be contingent on the reliability/availability allocated to SSCs in the risk model (or on performance of operators, where appropriate) used to support the proposed change in regulation. As such, reviewers should ensure that the chosen performance criteria are consistent with the level of performance allocated in the risk analysis.

When monitoring that is already being performed as part of the Maintenance Rule implementation or as part of other plant programs is also proposed for the current application, reviewers should ensure that the monitoring proposed is sufficient for the SSCs affected by the risk-informed application, and the performance criteria chosen are appropriate for the application in question.

As part of the evaluation of the licensee's monitoring program, reviewers should assess the proposed provisions for cause determination, trending of degradation and failures, and corrective actions. The program should be structured such that feedback of information and corrective actions is accomplished in a timely manner, and degradation in SSC performance is detected and corrected before plant safety can be compromised. In cases where monitoring detects degradation, there should be provisions for a trending and corrective action program, or for the SSCs to be refurbished, replaced, or tested/inspected more often (or a combination of these initiatives). The preferred initiative should be selected on the basis of determination regarding the cause of the degradation (whether it is generic, age-related, etc.). Reviewers should evaluate if the information gathered during monitoring activities is extensive enough to provide a timely indication of component degradation. Since many components are inherently quite reliable, the limited tests on a limited number of similar components may not provide adequate data, especially for newer plants where aging effects may not be detected until the proposed program is fully in place (and the advantages of a phased implementation are lost). One approach to ameliorate this concern would be to include performance data for similar SSCs at other plants with a range of operating times to expand the applicable database over a range of component ages. Such a program would be expected to improve the better chance of early detection of SSC reliability degradation.

Reviewers should evaluate the impact on plant risk and SSC functionality, reliability, and availability given the licensee's proposed implementation and monitoring plan. The benefits from the implementation and monitoring programs should be balanced against any negative impact on risk.

Finally, reviewers should consider the criteria to be applied in deciding what actions are to be taken in cases where performance falls below that predicted by the supporting evaluations. Corrective action procedures should be in place before implementation of the proposed program.

III.4 Element 4: Conduct Staff Evaluation of Submittal

In order for the staff to reach a conclusion regarding the acceptability of the proposed LB change on the basis of the review guidance presented in earlier sections, the licensee must submit or make available sufficient engineering and licensing information. In addition, the licensee should request appropriate regulatory action. 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 withdrawal of orders, and changes to programs pursuant to 10 CFR 50.54 (e.g., QA program changes under 10 CFR 50.54(a)). Reviewers should determine if (i) the form of the change request is appropriate for the proposed LB change, (ii) the licensee submitted the information required by the relevant regulation(s) in support of the request, and (iii) the request is in accordance with relevant procedural requirements. For example, license amendments should meet the requirements of 10 CFR 50.90, 50.91, and 50.92, as well as the procedural requirements in 10 CFR 50.4. Where the licensee submits risk information in support of the LB change request, that information should meet the guidance in Section 3 of RG 1.174.

Licensees have a choice of whether to submit results or insights from risk analyses in support of their LB change request. Where the licensee's proposed change is consistent with the currently approved staff positions, reviewers generally should reach their determination solely on the basis of traditional engineering analysis without recourse to risk information. (Reviewers may, however, consider any risk information submitted by the licensee.) Where the licensee's proposed change goes beyond currently approved staff positions or appears to constitute a special circumstance as described in Appendix D, reviewers should consider both information derived through traditional engineering analysis as well as information derived from risk insights. If the licensee does not submit risk information in support of a LB change which goes beyond currently approved staff positions, reviewers may request that the licensee provide this information. If the licensee chooses not to provide the risk information, reviewers will evaluate the proposed application using traditional engineering analysis and determine whether the licensee has provided sufficient information to support the requested change. If the licensee does not choose to address risk for a situation believed to create a special circumstance as described in Appendix D, reviewers should not issue the requested amendment until they have assessed the risk implications sufficiently to determine that there is reasonable assurance that the public health and safety will be adequately protected if the amendment request is approved.

In risk-informed change proposals, licensees are expected to identify SSCs with high risk significance which are not currently subject to regulatory requirements, or are subject to a level of regulation which is not commensurate with their risk significance, or voluntary actions that are key to decisionmaking. In addition, licensees are expected to propose LB changes that will subject such SSCs or voluntary actions to the appropriate level of attention, consistent with their significance. Application-specific regulatory guides set forth specific information on the staff's expectations on this issue. Reviewers should ensure that this application-specific guidance is followed. If there is no guidance, reviewers should determine whether any commitments for enhanced requirements/controls are appropriate for such SSCs or voluntary actions, and ensure that those commitments are reflected in the licensing basis.

Update of the Safety Analysis Report

Reviewers should ensure that the proposed changes, when approved by the staff, will be appropriately included in future updates to the licensee's safety analysis report. In addition, the licensee should identify important assumptions (including SSC functional capabilities and performance attributes) which play a key role in supporting the acceptability of the LB change. Since the continued satisfaction of these assumptions is necessary to maintain the validity of the safety evaluation, reviewers should verify that such assumptions are reflected by licensee commitments which are incorporated into the safety analysis report. Reviewers should also verify that the licensee has submitted revised FSAR pages, as necessary. This revision should include all the programmatic activities, performance monitoring aspects, and SSC functional performance and availability attributes which form the basis of the request. This material should also identify those SSCs for which performance should be verified (including nonsafety-related SSCs for which performance and reliability provide part of the basis for the LB change).

Considerations Related to the National Environmental Policy Act

In accordance with 10 CFR Part 51, the staff's review process should address environmental protection regulations, such as those from the National Environmental Policy Act (NEPA). Reviewers should use NRR Office Letter 906, Revision 1, and 10 CFR 51.25 to determine how the NEPA requirements are to be addressed. If it is determined necessary, an environmental assessment (EA) should be prepared to assess whether an environmental impact statement (EIS) is required, or whether the staff can reach a finding of no significant impact (FONSI). It is expected that, if all of the guidance and acceptance criteria provided in RG 1.174 are satisfied, the staff should normally be able to reach such a finding for the proposed change.

Table III-1 (page 1 of 3)

Questions to Assist in Establishing the Cause-Effect Relationship[4]

LEVEL 1 (INTERNAL EVENTS PRA)

Initiating Events

- Does the application introduce new initiating events?
- Does the application address changes that lead to a modification of the initiating event groups?
- Does the application necessitate reassessment of the frequencies of the initiating event groups?
- Does the application increase the likelihood of a system failure that was bounded by an initiating event group to the extent that it needs to be explicitly considered?

Success Criteria

- Does the application necessitate modification of the success criteria?
- Does the modification of success criteria necessitate changes in other criteria, such as system interdependencies?

Event Trees

- Does the application address an issue that can be associated with a particular branch, or branches on the event trees, and if so, is the branching structure adequate?
- Does the application necessitate the introduction of new branches or top events to represent concerns not addressed in the event trees?
- Does the application necessitate consideration of reordering branch points (i.e., does the application affect the sequence-dependent failure analysis)?

System Reliability Models

- Does the application impact system design in such a way as to alter system reliability models?
- Does the application impact the support functions of the system in such a way as to alter the dependencies in the model?
- Does the application impact the system performance and, if so, is that impact obscured by conservative modeling techniques?

Parameter Database

- Can the application be clearly associated with one or more of the basic event definitions, or does it necessitate new basic events?
- Does the application necessitate a specialized probability model (e.g., time-dependent model, etc.)?
- Does the application necessitate modifications to specific parameter values?
- Does the application introduce new component failure modes?
- Does the application affect the component mission times?
- Does the application necessitate that the plant-specific (historical) data be taken into account, and can this be easily achieved by an update of the previous parameters?
- Does the application involve a change which may impact parameter values, and do the present estimates reflect the current status of the plant with respect to what is to be changed?

Dependent Failure Analysis

- Does the application introduce or suggest new common cause failure contributions?
- Does the application introduce new asymmetries that might create subgroups within the CCF component groups?
- Is the application likely to affect CCF probabilities?

[4] Information from Section 3.3 of the EPRI "PSA Applications Guide" provided substantial input to this table.

Questions to Assist in Establishing the Cause-Effect Relationship

Human Reliability Analysis

- Does the application involve a procedure change?
- Does the application involve a new human action?
- Does the application change the available time for human actions?
- Does the application affect the human action dependency analysis?
- Does the application eliminate or modify an existing human action?
- Does the application introduce or modify dependencies between plant instrumentation and human actions?
- Is the application concerned with events that have been screened from the model, either in whole or in part?
- Does the application impact a particular performance shaping factor (PSF), or a group of PSFs, and are they explicitly addressed in the estimation approach (e.g., if the issue is to address training, is training one of the PSFs used in the human reliability analysis)?
- Does success in the application hinge on incorporating the impact of changes in PSFs and, if so, do the current estimates reflect the current status of these PSFs?
- Is it possible that the particular group of human error events that is affected by the change being analyzed has been truncated?
- Does the change address new recovery actions?

Internal Flooding

- Does the application affect the screening analysis (e.g., does the application result in the location of redundant trains or components into the same flood zone)?
- Does the application introduce new flooding sources or increase existing potential flood inventories?
- Does the application affect the status/availability of flood mitigation devices?
- Does the application affect flood propagation pathways?
- Does the application affect critical flood heights?
- Does the application affect timing considerations used in the flooding analysis (e.g., flood flow rates or flood egress rates)?

Quantification

- Does the application change any of the basic event probabilities?
- Does the application change relative magnitudes of probabilities?
- Does the application only make probabilities smaller?
- Is the new result needed in a short-time scale?
- Does the application necessitate a change in the truncation limits for the model?
- Does the application affect the "delete terms" used during the quantification process? (i.e., does the application introduce new combinations of maintenance actions or operating modes that are deleted during the base case quantification process using the delete function?)
- Does the application affect equipment credited for recovery actions (including credit for inter-system or inter-unit crossties)?

Analysis of Results

- Does the application necessitate an assessment of uncertainty, and is it to be qualitative or quantitative?
- Are there uncertainties in the application that could be clarified by the application of sensitivity studies?
- Does the application strategy necessitate an importance analysis to rank contributions?
- Does the application necessitate the performance of an importance, uncertainty, or sensitivity analysis of the base case PRA?

Plant Damage State Classification

- Does the application impact the choice of parameters used to define plant damage states?
- Do the key plant damage states (KPDSs) utilized adequately represent the results of the Level 1 analysis by including the plant damage states that have a significant frequency of occurrence?
- Have those plant damage states that have been eliminated in this process been assigned to KPDSs of higher consequence (e.g., likelihood of large early release)?

Table III-1 (page 3 of 3)

Questions to Assist in Establishing the Cause-Effect Relationship

LEVEL 2 (CONTAINMENT ANALYSIS)

- Have new containment failure modes identified by the application been addressed in the PRA? Are potential changes accounted for?
- Are any dependencies among containment failure modes being changed?
- Does the application involve mechanisms that could lead to containment bypass?
- Does the application involve mechanisms that could cause failure of containment isolation?
- Does the application directly affect the occurrence of any severe accident phenomena?
- Does the application necessitate use of risk measures other than large early release?
- Does the application change equipment qualification to the point where it affects timing of equipment failure relative to containment failure?
- Does the application affect core debris path to the sump / suppression pool or to the other portions of the containment?
- Do the selected source term categories adequately represent the revised containment event tree (CET) endpoints? Are CET endpoint frequencies changed enough to affect the selection of the dominant/representative sequence(s) in the source term binning process?
- Does the application affect the timing of release of radionuclides into the environment relative to the initiation of core melt and relative to the time for vessel rupture?

LEVEL 3 (CONSEQUENCE ANALYSIS)

- Does the application necessitate detailed evacuee doses?
- Are individual doses at specific locations needed for this application?
- Is evacuation or sheltering being considered as a mitigation measure?
- Are long-term doses a consideration in this application?

EXTERNAL EVENTS PRA

- Does the application introduce external hazards not previously evaluated?
- Does the application increase the intensity of existing hazards significantly?
- Are design changes modifying the structural response of the plant being considered?
- Does the change impact the availability and performance of necessary mitigation systems for an external hazard?
- Does the application significantly modify the inputs to the plant model conditioned on the external event?
- Are changes being requested for systems designed to mitigate against specific external events?
- Does the application involve availability and performance of containment systems under the external hazard?

LOW POWER and SHUTDOWN PRA

- Does the application introduce new initiating events or change the frequencies of existing events?
- Does the application affect the scheduling of outage activities?
- Does the application affect the ability of the operator to respond to shutdown events?
- Does the application affect the reliability or availability of equipment used for shutdown conditions?
- Does the application affect the availability of equipment or instrumentation used for contingency plans?

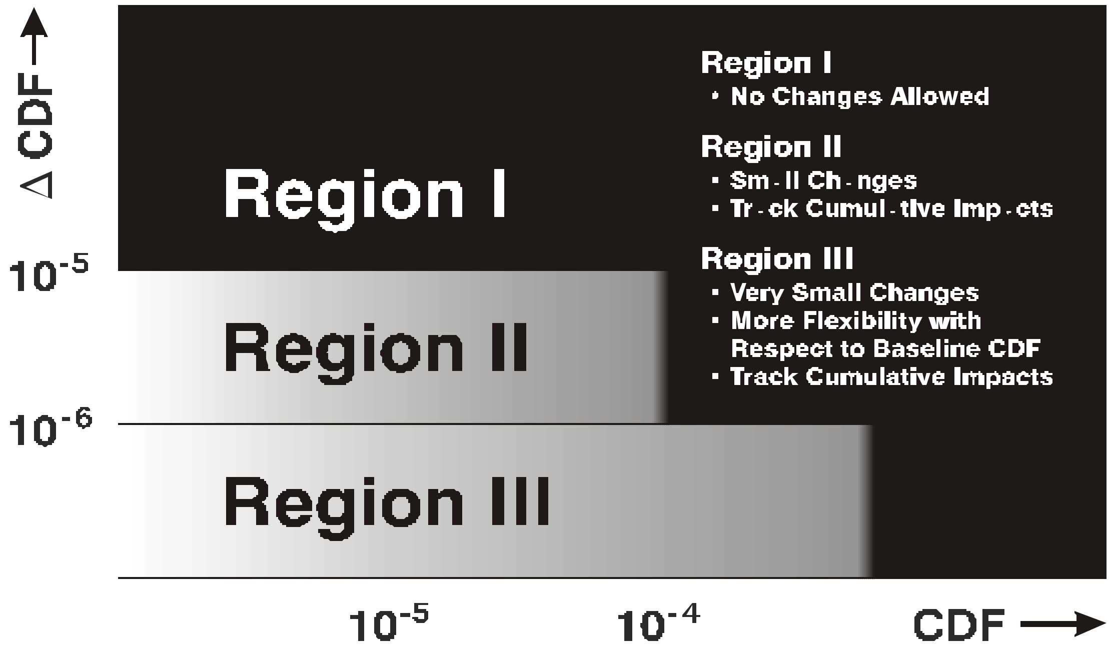

Figure III-1 Acceptance Guidelines* for Core Damage Frequency (CDF)

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

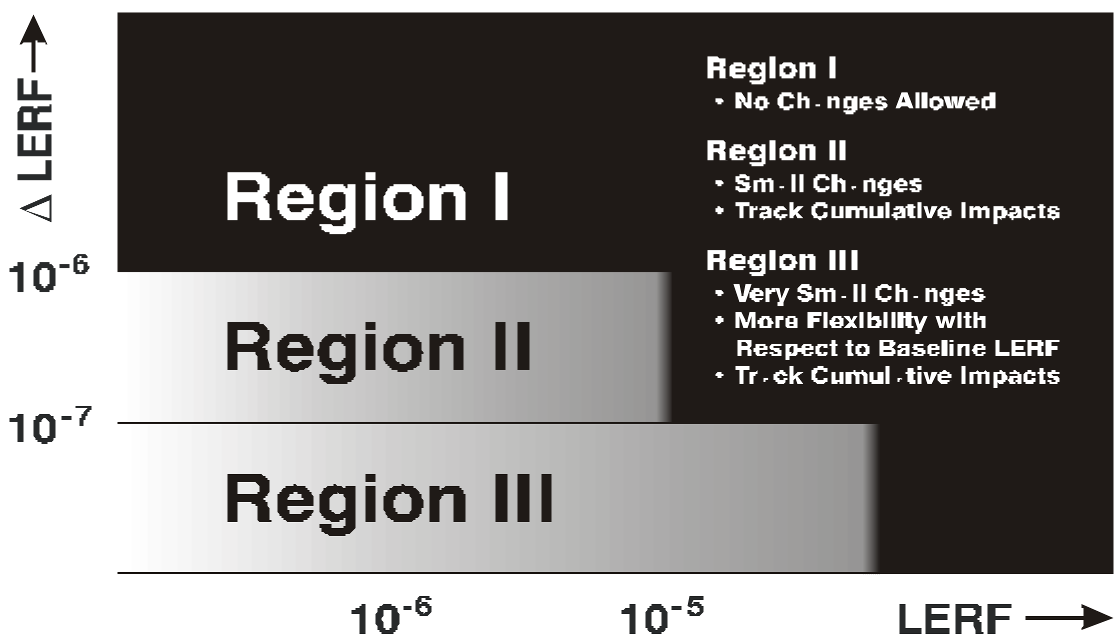

Figure III-2 Acceptance Guidelines* for Large Early Release Frequency (LERF)

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

IV. EVALUATION FINDINGS

The results of the reviewers' evaluation should reflect a consistent and scrutable integration of the probabilistic considerations and traditional engineering considerations provided by the licensee or applicant and developed independently by the reviewers. To reach a finding of acceptability, reviewers will generally need to show that in light of a small or non-existent increase in risk and a reduced level of conservatism, defense-in-depth and sufficient safety margins are maintained. Findings of acceptability should be supported with logical bases built from an evaluation of the considerations given in Section III of this SRP chapter. Reviewers should also confirm that sufficient information is provided in accordance with the requirements of this SRP chapter, and that the evaluation supports the following conclusions, to be included in the staff's safety evaluation report.

General

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

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

- The proposed change maintains sufficient safety margins.

- When proposed changes result in an increase in CDF or risk, the increases are small and are consistent with the intent of the Commission's Safety Goal Policy Statement.

- The impact of the proposed change is monitored using performance-based strategies.

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

- The scope and quality of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed LB change are appropriate for the nature and scope of the change and are derived on the basis of the as-built, as-operated and as-maintained plant, including operating experience at the plant.

- ~~The portions of the plant-specific PRA relevant to the application should contain the characteristics and attributes of a PRA as defined in Appendix A to Regulatory Guide 1.174. It should also be subjected to an independent peer review to determine whether it contains those characteristics and attributes.~~

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

- The plant-specific PRA supporting the licensee's proposals has been subjected to quality controls such as an independent peer review or certification.

- Appropriate consideration of uncertainty has been given to analyses results and interpretation of findings, including the use of a program of monitoring, feedback, and corrective action to address significant uncertainties, where applicable.

- CDF and LERF are used as bases for probabilistic risk assessment guidelines for addressing Principle 4. If the Commission's Safety Goal QHOs have been used in lieu of LERF, the implementation of such an approach included justification of the methods and assumptions used in the analysis and treatment of uncertainties.

- Increases in estimated CDF and LERF resulting from proposed LB changes are limited to small increments, and the cumulative effects of such changes are tracked and considered in the decision process.

- The acceptability of the proposed changes has been 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 are clearly documented and available for public review.

<u>Definition of the Proposed Change</u>

- Adequate traditional engineering and probabilistic evaluations are available to support the proposed LB change. Plant-specific and relevant industry data and operational experience also support the proposed change.

- Cause-effect relationships have been identified to adequately link the application with the evaluation models, and the proposed models can effectively evaluate or realistically bound the effects of the proposed change.

- Information from engineering analyses, operational experience, plant-specific performance history have been factored into the decisionmaking process.

<u>Evaluations of Defense-In-Depth Attributes and Safety Margins</u>

- Defense-in-depth is preserved (for example, system redundancy, diversity, and independence are maintained commensurate with the expected frequency and consequence of challenges to the system; defenses against potential common cause failures are maintained and the introduction of new common cause failure mechanisms is assessed; and defenses against human errors are maintained).

- Sufficient safety margins are maintained (for example, NRC-approved codes and standards are met or deviations justified; and safety analysis acceptance criteria in the LB are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty).

- Current regulations have been met, or the proposed exemption is acceptable.

<u>Scope of Risk Analysis</u>

- The licensee's risk analysis satisfactorily addresses all mode/initiator combinations, **or**

- The licensee's risk analysis does not analyze all mode/initiator type combinations. However, in each instance, the licensee has demonstrated that

- suitably redundant and diverse plant response capability is maintained for significant initiators in these modes, **and**
- sufficient elements of the plant response capability are subject to programmatic activities to ensure suitable performance

Level of Detail of Risk Analysis

- The PRA is detailed enough to account for important system and operator dependencies.

- Risk insights are consistent with the level of detail modeled in the PRA.

Quality of the PRA

- There is reasonable assurance that the PRA is of sufficient quality to support the conclusions as they impact the decision, as shown by the licensee's process to ensure quality, including an independent peer review, and by a focused-scope application-specific review by the staff.

- Results are robust in terms of uncertainties and sensitivities to the key modeling parameters.

- Key performance elements for the application have been appropriately classified and performance is backed up by licensee actions.

Evaluation of Risk Impact

- If the risk-informed application assesses whether it meets Principle 4 by evaluating the change to risk quantitatively, then the following applies:

  - The application either decreases plant risk, or if an application increases risk, the increase is within the guidelines defined in RG 1.174. The cumulative and synergistic effects on risk from the present and previous applications have been addressed. Licensee risk management practices are being followed to minimize the risk from plant operations.

  - An appropriate consideration of uncertainties is provided in support of the proposed application. The licensee showed that even taking into account the uncertainties in the analysis, the evaluation of the change in risk was robust in that there can be confidence in the conclusions drawn with respect to nature of the change compared with the acceptance guidelines. This argument was supported either by explicit propagation or by a qualitative and/or sensitivity analysis showing that no event contributing to the change in risk is subject to significant uncertainty.

- If the risk-informed application is based on a qualitative assessment of the change to risk, the application is shown to result in a decrease in plant risk, or is risk neutral, or CDF and LERF increases are shown to be acceptable on the basis of bounding evaluations or sensitivity studies.

Integrated Decisionmaking Process

- Results from traditional engineering analyses and risk analyses have been used to ensure that the principles for risk-informed decisionmaking have been met.

- Potential analysis limitations, uncertainties and conflicts are resolved by use of conservative results, or by use of appropriate implementation and monitoring strategies, or by use of appropriate compensatory measures.

- The integrated decisionmaking process is well-defined, systematic, repeatable, and scrutable.

- The scope of implementation of the change is appropriate for, and commensurate with, the level of confidence in the results of the analysis.

Implementation and Monitoring Strategies

- The implementation process is commensurate with the uncertainty associated with the results of the traditional and probabilistic engineering evaluations.

- A monitoring program which could adequately track the performance of equipment covered by the proposed licensing changes was established. It was demonstrated that the procedures and evaluation methods will provide reasonable assurance that performance degradation will be detected and that the corrective action plan will ensure that appropriate actions can be taken before SSC functionality and plant safety is compromised. Data from similar plants will be used if needed.

- In addition to the tracking of performance of SSCs affected by the application, the performance monitoring process also includes tracking the performance of SSCs which support the underlying basis for the decisionmaking.

Licensee Submittal

- The submittal includes sufficient information to support conclusions regarding the acceptability of the proposed change.

- The appropriate regulatory action was requested. In addition, pertinent information on the LB change will be included in the safety analysis report, technical specifications, or license conditions, as necessary.

- The licensee has appropriately committed to the important programmatic and performance assumptions in the PRA and engineering analyses which served as the basis of the LB change. These include compensatory actions used to justify the change and any new regulatory requirements for high risk significant SSCs not otherwise subject to existing requirements, commensurate with their risk significance. These commitments are reflected in revisions to the safety analysis report and/or technical specifications, or the staff has imposed appropriate licensee conditions.

V. IMPLEMENTATION

The preceding material is intended to provide guidance to applicants and licensees regarding the NRC staff's plans for using this SRP chapter for reviews of applications involving risk-informed changes to the plant's design, operations and other activities that require NRC approval.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method for demonstrating that a proposed LB change is acceptable, the method described herein will be used by the staff in its evaluation of such changes.

VI. REFERENCES

1. NRC Policy Statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," 60 Federal Register (FR) 42622, August 16, 1995.

2. "Framework for Applying Probabilistic Risk Analysis in Reactor Regulation," U.S. Nuclear Regulatory Commission, SECY-95-280, November 27, 1995.

3. "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment," U.S. Nuclear Regulatory Commission, SECY-94-219, August 19, 1994.

4. "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide (RG) 1.174, July 1998.

5. "Risk-Informed Regulation Implementation Plan," U.S. Nuclear Regulatory Commission, SECY-00-0213, October 26, 2000; updated as SECY-01-0218, December 5, 2001.

6. "PSA Applications Guide," Electric Power Research Institute, EPRI-TR-105396, August 1995.

7. Letter to Samuel J. Collins, NRC, from Ralph E. Beedle, NEI, with attached "Probabilistic Risk Analysis (PRA) Peer Review Guidance," Rev. A3, NEI 00-02, Prepared for NEI Risk-Based Applications Task Force by WOG/Westinghouse Electric Co., and B&WOG/Framatome Technologies, Inc., April 24, 2000.

8. "Rulemaking Plan for Risk-Informing Special Treatment Requirements," SECY-99-256, October 29, 1999.

APPENDIX A

GUIDANCE FOR A FOCUSED-SCOPE APPLICATION-SPECIFIC PRA REVIEW

As stated in Section III.2.2.4 of this SRP chapter and in Section 2.2.3 of RG 1.174, PRAs that are used in risk-informed submittals to determine risk significance or risk impact should be shown to be of adequate quality. In risk-informed regulation (RIR), licensee submittals are expected to utilize an integrated process which combines risk insights from a PRA, together with insights from traditional engineering analyses, supported by performance monitoring and feedback. The quality of the PRA required to support this process is commensurate with the roles the risk insights play in the final decisionmaking.

Staff evaluation of a licensee's risk-informed application submittal is expected to include a review of the licensee's process for PRA quality assurance. Where necessary, this should be supplemented by a general review of the event and fault tree models, data on SSC failures and common cause failures, mission success criteria, initiating event analysis, human reliability analysis, and sequence quantification including the analysis of uncertainties. These reviews should be sufficiently detailed to give the staff confidence that the PRA appropriately reflects the plant's design and actual operating conditions and practices. Results from previous staff reviews (e.g., from prior applications or from IPE/IPEEE reviews) and from industry reviews (e.g., from independent peer reviews, certification processes, or cross comparisons) should be used, as appropriate.

In addition to the general overall review described above, staff reviewers are expected to perform a focused-scope review of the risk analysis on an application-specific basis. This appendix provides review guidance for the likely elements of a PRA which may affect or be affected by proposed changes to the LB. Reviewers should choose the relevant parts of this appendix, guided by the application-specific SRP chapters (where available) and by the cause-effect relationship described in Section III.2.2.1 of this SRP chapter.

For additional background on the PRA review, the reader is referred to the bibliography provided in Section A.11 of this appendix.

A.1 <u>Initiating Event Analysis</u>

a. Areas of Review

Whether or not a PRA includes a particular initiating event depends on the scope of the PRA, the frequency of the given event, the plant systems or other features available to mitigate the event, and the consequences of the event if unmitigated. Proposed plant changes could affect the frequency of initiating events, the probability of mitigating event initiators and, in some cases, event consequences. In addition, plant changes could potentially introduce new initiating events or increase the importance of events that were previously screened out.

b. Review Guidance and Procedures

For risk-informed applications, reviewers should determine if the licensee followed a systematic approach to determine if initiating events and anticipated plant response are affected by the proposed changes. Reviewers should also determine if the licensee's process includes provisions to evaluate whether the proposed changes can (i) increase the frequency of an initiator already included in the PRA; (ii) increase in the frequency of initiators that were initially screened out in the PRA; (iii) introduce new initiating events; or (iv) affect the grouping of initiating events. These considerations are discussed in more detail in the following paragraphs.

Applications that change the frequency of an initiator or the ability of the plant to respond to event initiators are relatively easy to model in the risk analysis if the initiators are already included in the base analysis. In such cases, the licensee should have evaluated the impact of the changes directly from the risk model.

In cases where initiators are not included in the original risk analysis based on screening analyses, the licensee should have determined if initiating events previously screened out because of low frequency might now be above the screening threshold as a result of a proposed application. Plant changes could increase the frequency of initiating events that were relatively infrequent to begin with, or these changes could affect SSCs or operator actions that were credited with the satisfactory mitigation of initiating events. If initiating events increased in frequency as a result of an application to the point where it became important (i.e., could no longer be screened out), reviewers should verify that the licensee has modified the scope of the analysis to reflect this change.

Low frequency of an event, by itself, is not usually sufficient as a criterion for screening purposes. The consequences of non-mitigation of the events also play a big part in this process. For example, interfacing system loss-of-coolant accidents (ISLOCAs) are often assessed as low-frequency events. However, because of their impact on public health and safety, these ISLOCAs can be important. Therefore, for potentially high-consequence events, even if the event frequency is below a screening criterion, the features that lead to the frequency being low (for example, surveillance test practices, startup procedures, etc.) should be taken into account in reviews of PRA applications.

The licensee should also have evaluated proposed plant changes to determine if the changes could result in initiators that are not previously analyzed in the PRA. For example, changes might enhance the potential for spurious operation of components which might, in turn, cause initiating events, or changes might increase the likelihood for operator errors of commission which could result in plant trips. If the licensee identified mechanisms for producing new initiators, reviewers should ensure that the licensee added those initiators to the risk analysis so that their impacts can be analyzed.

In PRAs, initiating events are usually grouped according to the systems required to respond to the transient. This implies that success criteria for plant systems and operator responses are similar for all events in a group. In addition, events may be screened out when it can be shown that they are bounded in probability and consequence by other similar events. In evaluating risk-informed applications that affect initiating events, reviewers should ensure that grouping criteria used in the base analysis have not been invalidated by the proposed plant changes or, in the case where this is not true, the licensee has made appropriate changes to the event groupings.

Finally, the reader should note that many PRAs model initiating events as single basic events or "black boxes." In RIR, it is preferred that the licensee model initiating events (especially those that result from the loss of support systems) using a fault tree (or equivalent) approach so that system dependencies are fully understood and accounted for. If this is not the case, reviewers should be aware of the combination of SSC failures or other events that could lead to the "failure" of the black box. This would lead to a better understanding of the risk contributors and is especially important in risk categorization applications.

c. Evaluation Findings

Reviewers should verify that the information provided and review activities conducted support the following conclusions:

- The licensee has adequately considered the effects of proposed changes on the frequencies of initiating events analyzed and those previously screened out.

- The licensee has demonstrated that the changes do not result in new initiating events or, if new initiators have been identified, these have been added to and analyzed in the risk model.

- The licensee has accounted for the proposed changes in the grouping of initiating events.

- The decisionmaking process considered the dependencies between the initiating events and the plant's mitigation systems.

A.2 <u>Accident Sequence Analysis (Event Trees)</u>

a. Areas of Review

Although the evaluation of risk change from most applications will usually not necessitate changes to the event tree structure or logic, reviewers should be aware that there will be some changes, particularly those involving changes to plant procedures, which might cause a restructuring of the event sequence logic.

In addition, the application may isolate part of the PRA that is dependent on specific initiating events. Thus, these initiating events and their associated event trees would have a proportionately greater impact on the evaluation of the change in risk. In this case, these event trees could be candidates for a higher level of scrutiny. For example, if the changes involved the addition or subtraction of a diesel generator, the review would focus on the station blackout event tree and its associated structure and logic. Similarly, if changes involve modification to procedures to cross-tie electrical buses, the review might focus on the loss of offsite power event trees.

b. Review Guidance and Procedures

Event tree sequence models are used to model the responses of plant systems and operations personnel to initiating events. When the LB change request requires the review of event trees, it is important that reviewers become familiar with their structure, and with the assumptions embedded in them. In particular, it is important to identify assumptions or approximations that might impact the application. Such assumptions and approximations are not always explicitly documented. The guidance provided below discusses approaches that reviewers can adopt to assess the appropriateness of the modeling of the LB change in the event trees.

Reviewers should familiarize themselves with the structure of the event trees and the associated assumptions that are used in the construction of the event trees. Specific issues to consider should include the conditions created by the initiator and the chronological requirements for systems operation and/or operator responses for the different event tree branches. Reviewers should be satisfied that, if simplifications or assumptions were made in the structure and logic of the event trees, these would remain justifiable in light of the LB change.

Reviewers should also study the functional and physical dependencies for each phase of the sequence and, at the same time, the interaction between operators and systems as the sequence unfolds. The timing of the events and time dependencies should also be understood. A review of the general structure and philosophy underlying the pertinent plant emergency and abnormal operating procedures will provide valuable insight on the validity of the event tree structure and logic.

Specifically, reviewers should ensure that the following factors are addressed in the evaluation of the LB change:

- The event trees reflect changes (if any) to the initiating event groupings.

- The models and analyses are consistent with the as-built and as-operated plant, i.e., the functions necessary for safe shutdown are included, relevant systems are credited for each function, and plant emergency operating procedures (EOPs) and abnormal operating procedures (AOPs) are correctly represented. In addition, where the proposed change affects any of these elements, the change is properly modeled.

- Changes to the plant's design or operations could affect the dependencies (functional, phenomenological, and operational) among the top events in event trees. Section A.4 of this SRP chapter presents additional detail concerning the review of the dependent failure analysis.

- Time-phased evaluation is normally included for sequences with significant time-dependent failure modes (e.g., batteries for station blackout sequences) and significant recoveries (e.g., AC recovery for SBO sequences). The impact of the change on event timing that could affect the structure or logic of the event trees should be understood.

- It is expected that the success criteria used in the event trees will not be affected by many of the changes to the plant's design and operations. In cases where changes could affect the success criteria for front-line or support systems, reviewers should verify that these criteria (hardware requirements, number of trains required, etc.) remain consistent with the required performance criteria (flow, response time, etc.) related to functional requirements. However, even in cases where the change does not affect the success criteria, reviewers should be aware that the success criteria used in the base PRA analysis could affect the conclusions made in the evaluation of the risk change. For example, a component in a three-train system might not be risk-significant if mission success was contingent on the successful operation of one out of the three trains, but this component could become more risk-significant if the success criterion was two-out-of-three or three-out-of-three trains. Section A.5 discusses the review of the success criteria used in accident sequence modeling.

c. Evaluation Findings

Reviewers should verify that information provided and review activities conducted support the following conclusions:

- The licensee has adequately considered the effects of proposed changes on the structure and logic of the event trees.

- The licensee has addressed the effects of the application on sequence dependent failure analysis, sequence timing, and success criteria.

A.3 System Modeling Analysis (Fault Trees)

a. Areas of Review

Fault trees are used to depict the logical interrelationships of credible plant events (component hardware failures, human errors, or other pertinent events) that can lead to particular failure modes of plant systems in the context of their environment and operation. In RIR, the majority of proposed changes would only be expected to impact the parameters that are used to quantify the event probabilities modeled in the fault trees. In such cases, the change will not affect the fault tree logic models themselves. However, in cases where the change relates to a system design change, or where the licensee is proposing temporary changes that require reconfiguration of the system into ones that are not currently modeled, the revised fault trees should be one focus of the staff's review.

Other considerations of which reviewers should be aware in the area of system analysis are whether the application can impact support functions in such a way as to alter the dependencies in the model, and whether the application can impact system performance to an extent that would require changes to the fault tree logic or modeling assumptions.

b. Review Guidance and Procedures

When the review of one or more of the system logic models becomes necessary, this review should include a study of the appropriate system notebooks from the base PRA to understand the modeling characteristics that may be affected by the change. It should also include an evaluation of the licensee's process for modeling the system change as well as a spot-check of the revised system models and results. Reviewers should verify that, in modeling the change, the licensee appropriately modified the system logic models to reflect changes in the plant's configuration including changes to the system design, system performance characteristics, system alignments, operational procedures, and operational philosophies. In particular, reviewers should address the following considerations:

- The analysis of the change should account for the effects of the change on the definition of system success. That is, if the proposed application affects component configurations, expected operability conditions, failure modes and their effects, and alternative success and potential failure paths, these should be taken into account. In addition, the licensee should show that the justification used in the original analysis to exclude components, component failure modes, or flow diversion paths, etc. remain valid in light of the proposed change. The analysis should also identify and account for changes that could affect environmental conditions that could cause system failure (e.g., room temperature, containment pressure, etc.).

- The analysis should account for interfaces with other systems and dependence on support functions; this is particularly important if dependencies on motive power, control power, component cooling, room cooling, or any interlocks have been altered by an application. Other dependencies that licensees should consider include the dependency on automatic system initiation and the conditions that must exist for automatic start, essential manual actions to initiate or control the system, and the resources required to fulfill mission success (e.g., water sources, air, fuel oil, etc.). When applicable, licensees should factor these dependencies into the analysis of the change.

- When proposed changes deal with proceduralized test and maintenance actions or applicable technical specification conditions, the modeling of test and maintenance unavailabilities and the modeling of restoration errors for the affected systems/components should be reviewed. Changes to the frequency of each test or maintenance activity, its approximate duration, the components repositioned for the action, the verification activities post test and maintenance, and the availability of the system during the test procedure should have been factored into the change analysis.

- Operational history (i.e., plant-specific operational experience) should be considered in the review of the system models and especially in the review of how the proposed change will affect system operation. Considerations like recurring check valve problems (e.g., back-leakages), water hammer events, or flow blockages by sludge or debris should also be considered in the analysis.

- The potential for common cause failures including those potentially resulting from the change should have been evaluated and modeled where appropriate. Review guidance for the evaluation of common cause failures is provided in Section A.7 of this SRP chapter.

- The function of the modeled system should remain consistent with that required in the event tree models. Success criteria and event sequence conditions should be correctly modeled and consistent with the definition in the event trees.

When fault tree solutions in the form of function cutsets are available, an efficient way to review for the logic in system models is to study the cutsets produced by the solution of the linked fault trees (i.e., the fault tree formed by linking the support system fault trees to the system fault tree). In performing this visual inspection, reviewers should compare the results with expectations based on their understanding of functional and support system dependencies. The effects of events such as operator actions or common cause failures can also be easily verified by an inspection of the function cutsets. When expected combinations of failures are not present, reviewers should check to see if these failures have been modeled, or if they have been truncated during model solution, or if the fault tree logic is incorrect (e.g., an AND gate in place of an OR gate). In short, a review of cutsets can be one way to focus further reviews on other parts of the system modeling analysis.

c. Evaluation Findings

Reviewers should verify that information provided and review activities conducted support the following conclusion:

- The evaluation adequately reflects changes in the plant hardware or procedures, including changes to the system design or alignments, system performance characteristics, support system dependencies, and operational procedures or operational philosophies. Where applicable, these changes are appropriately included in the PRA system models.

A.4 Dependent Failure Analysis

a. Areas of Review

Accident progression models and system models should correctly account for dependencies between systems and operator actions needed for accident mitigation. Proposed changes to the plant's design or operations could affect these dependencies; therefore, the evaluation of the risk change should also consider system-operator dependencies. However, since the modeling of these dependencies requires detailed knowledge of the plant systems and procedures, it will not be practical (nor is it intended) for reviewers to verify that all dependencies have been included in the change evaluation. Instead, reviewers should verify that the evaluation utilized a comprehensive and systematic process to look for these dependencies. Reviewers should rely on their experience with similar change analyses (when applicable) or with PRAs of similar plants, but should be aware that dependencies are in many cases plant-specific, and will depend on plant-specific system capabilities and interactions, procedural guidance, and timing of potential accident sequences.

b. Review Guidance and Procedures

Review guidance in this section consists of a discussion of the dependencies that could be important and that could be affected by changes to the plant's design or operations. Although most changes will not alter the original PRA dependent failure analysis, some design or procedure changes could introduce new dependencies or affect existing ones. Therefore, reviewers should be cognizant with regard to the following types of dependencies that could exist and could affect the results of the change analysis:

Functional Dependencies: These dependencies occur because the function of one system or component depends on that of another system or component. Functional dependencies include interactions which can occur when the change in the function of a system or component causes a physical change in the environment which results in the failure of another system or component. Functional dependencies include the following examples:

- shared component dependencies (e.g., systems or system trains that depend on a common intake or discharge valve)

- actuation requirement dependencies (e.g., systems that depend on common actuation signals, common actuation circuitry, or common support systems like AC or DC power or instrument air for initiation or actuation) and conditions needed for actuation (e.g., low RPV water level).

- isolation requirement dependencies (e.g., conditions that could cause more than one system to isolate, trip, or fail) including environmental conditions (temperature, pressure, and/or humidity), temperature and pressure of fluids being processed, water level status, and radiation levels.

- power requirement dependencies (e.g., systems that depend on the same power sources for motive power)

- cooling requirement dependencies (e.g., systems that depend on the same room cooling subsystem, or the same lube oil cooling subsystem, or systems that depend on the same service water or component cooling water train for cooling)

- indication requirement dependencies (e.g., systems that depend on the same pressure, temperature, or level instrumentation for operation)

- phenomenological effect dependencies (e.g., conditions generated during an accident sequence that influence the operability of more than one system), including generation of harsh environments that result in protective trips of systems, loss of pump net positive suction head (NPSH) when containment heat removal is lost, clogging of pump strainers from debris generated during a LOCA, failure of components outside the containment following containment failure attributable to harsh environment inside the containment, closure of safety relief valves in BWRs on high containment pressure, and coolant pipe breaks or equipment failures following (or resulting from) containment failure

- operational dependencies (e.g., unavailability of the suppression pool cooling mode for a train of the residual heat removal system when the system is in the low pressure coolant injection mode)

Reviewers should look for evidence that the licensee properly considered the above types of dependencies in the evaluation of the change. In most cases, these dependencies should be explicitly included in the fault tree or event tree logic models; however, in some cases, a qualitative evaluation process may be sufficient.

Human Interaction Dependencies: These dependencies could become important contributors to risk if operator error can result in multiple component failures. Past PRAs show that the following plant conditions could lead to human interaction dependencies that can become important:

- tests or maintenance that require multiple components to be reconfigured

- multiple calibrations performed by the same personnel

- post-accident manual initiation (or backup initiation) of components that require the operator to interact with multiple components

Reviewers should verify that the licensee's evaluation of risk from proposed changes to plant procedures or changes to operator training included a process to identify these (or similar) activities, and that the licensee evaluated the activities that could be risk contributors.

Component Hardware Failure Dependencies: These dependencies, usually referred to as common cause failures (CCFs), cover the failures of usually identical components which may be caused by design, manufacturing, installation, calibration, or operational deficiencies. CCFs are treated quantitatively by common cause failure probabilities or other dependence quantification approaches. Section A.7 of this SRP chapter presents review guidance related to CCFs.

Spatial Dependencies: Multiple failures could be caused by events that fail all equipment in a defined space or area. These spatially dependent failures include those caused by internal flooding, fires, seismic events, missiles (e.g., turbine missiles), or any of the other external event initiators. In cases where these events could affect the results of the change evaluation, and where these events are not modeled in the PRA, the dependencies resulting from the unmodeled initiators should be evaluated qualitatively as part of the integrated decisionmaking process. Section III.2.2 of this SRP chapter discusses the required scope of the PRA in more detail. In addition, the change request should include the licensee's consideration of the common influences on component operation such as adverse environment (including excessive temperature, humidity, radiation), inadequate space, inadvertent or spurious sprinkler operation, or routine equipment travel near major components. Reviewers should verify that the change request has used a systematic process to identify potential spatial challenges that could result in multiple failures of SSCs.

c. Evaluation Findings

Reviewers should verify that information provided and review activities conducted support the following conclusion:

- Dependencies between system and operator interactions have been properly accounted for in the evaluation of the proposed change. Where appropriate, these dependencies have been included in the accident progression models (event trees) and the system analysis models (fault trees).

A.5 Determination of Success Criteria

a. Areas of Review

Guidance in the PRA policy statement and in RG 1.174 stipulates that realistic analysis should be used in PRA implementation. The following discussion is intended to sort out what is meant by "realistic" analysis of success criteria by reference to SAR analysis.

In order to fulfill its intended purpose, SAR analysis is ordinarily based on a set of assumptions containing significant embedded conservatisms. SAR analysis also reflects a postulated single active failure, in addition to whatever event initiated the sequence. When an SAR analysis shows a successful outcome, there is good reason to believe that (apart from beyond-single-failure scenarios) the system will meet or exceed performance requirements for the initiating event considered.

Applying the SAR mission success criterion in a PRA would be conservative, in the sense that the probability of failure to meet this performance standard would be greater than probability of failure to meet a more realistic performance standard. However, re-analyzing event sequences with conventional SAR tools would be too burdensome to apply to the large number of scenarios that are defined in the course of a PRA. In addition, the rather specialized computer codes used in SAR analysis may not be appropriate in beyond-single-failure scenarios. Traditionally, development of mission success analyses in PRAs has ranged from the use of faster running models that might not have the same level of quality assurance as the conventional SAR tools, to the extrapolation of results from analyses performed on similar plants.

In order to satisfy the Commission's guideline, then, reviewers should find that the licensee has not distorted the PRA insights by using a systematically conservative bias in mission success criteria, and that mission success criteria used to justify changes to the plant's design or operations have a sound technical basis.

b. Review Guidance and Procedures

When it is determined that the results and conclusions of a risk-informed application are especially sensitive to the choice of mission success criteria, or if the modeling is particularly controversial, reviewers should evaluate the relevant success criteria and the basis for each.

If the basis is analytical, it may be appropriate to evaluate of the code and the input data used. When it is determined that the computer codes used have not received adequate licensee or other industry review, closer examination of the models should also be considered.

The models, codes, and inputs used to determine mission success criteria should meet QA standards that are consistent with generally accepted methods. Standards should include configuration control of the analysis inputs and results. The standards do not have to be the same as the standards applicable to SAR analysis, but they should be explicit (i.e., engineering calculations and codes should be verified and quality assured) and they should be formalized as part of the licensee's QA program.

In cases where the basis for the success criteria is lacking, reviewers should either request additional licensee justification or seek independent analysis. Licensee justification could include the use of alternative plausible models to justify the conclusions (thus addressing the model uncertainty), or the redesign of the change such that the change is not affected by the choice of success criteria.

Some mission success criteria can validly be extrapolated between similar plants when a firm basis for the criteria is created at the first plant and when the licensee shows that plant-specific features do not invalidate the comparison.

On an application-specific basis, reviewers should determine whether the definition of the system success criteria will be affected by the application-specific elements or by the elements in the same minimal cutset or accident scenario as the application-specific element. Reviewers should ensure that the success criteria are not so optimistic that they underestimate the required number of components (i.e., overestimate the size of the minimal cutset).

c. Evaluation Findings

In cases where conclusions are sensitive to the mission success criteria, the staff's safety evaluation report should contain findings equivalent to the following:

- A technical basis has been established for the mission success criteria used in the analysis. Analytical elements of the technical basis have received an appropriate level of configuration control and quality assurance. Where comparison with analogous criteria from other plants is possible, this comparison has been justified.

A.6 Use of Appropriate Data

a. Areas of Review

In risk-informed applications, it is important that the licensee use appropriate SSC failure data. While plant-specific data is preferred, for plants with little operating history, the only choice might be the use of generic data. Furthermore, when the impact of the change is being modeled as a modification of parameter values, sufficient plant-specific data may not exist to support the modification. The data- related issues are summarized as follows: a) if the impact of the application is to be modeled as a change in parameter values associated with basic events representing modes of unavailability of certain SSCs, these changes should be reasonable and should be supported by technical arguments including plant-specific and generic operational information (when available); and b) the impact of the change should neither be exaggerated nor obscured by the parameter values used for those SSCs unaffected by the change.

b. Review Guidance and Procedures

It is to be expected that, for a PRA that has undergone a technical review, parameter values will have been judged to be appropriate, whether they have been evaluated using generic or plant-specific data. However, since the review was focused on the PRA as a base case model, a different perspective on the appropriateness of parameter values may be required for specific applications. Therefore, in evaluating PRA applications, reviewers should focus on those parameter values that have the potential to change the conclusions of the analysis. For example, parameters associated with SSCs that appear in the same cutsets or scenarios as the affected SSCs have the potential to distort the conclusions by decreasing the assessed importance of the change if their values are too low, or by increasing it if their values are too high. Similarly, parameters that contribute to the cutsets or scenarios that do not contain affected SSCs can decrease the importance of the change by being too high, or increase it by being too low.

The failure rates and probabilities used, especially those that directly affect the proposed application, should appropriately consider both plant-specific and generic data. The staff expects that these values will be consistent with generally accepted values from PRAs of similar plants, or the licensee should justify significant deviations on the basis of plant-specific factors. "Significant" in this context can be defined as no greater than a factor of 3 for the mean values of the failure rate or failure probability. The focus of the review should be on those parameter values that have a significant impact on the results as discussed above, and that deviate significantly from the generally accepted norm.

If the reviewer decides that a more detailed review of the parameter values is appropriate, the following guidance applies. For plant-specific data, reviewers should determine how the licensee used plant records to estimate the number of events or failures, the number of demands, and the operating or standby hours. Reviewers should verify the consistency between the definitions of failure modes and component boundaries used in the risk analysis and the corresponding definitions used in the plant records. When reviewing generic data, it is important to verify that the plant component is typical of the generic industry component. In cases where generic failure rates are used in combination with plant-specific data like test intervals, reviewers should verify that the generic data are applicable for the range of plant data used.

When evaluating the impact of the change, it is important for reviewers to recognize the assumptions that have gone into developing the PRA model. For example, two models are commonly used for events representing the unavailability of a standby component on demand; the standby failure rate model and the constant probability of failure on demand model. The constant probability of failure on demand parameter may be estimated on the basis of an assumed number of demands, implying an average test interval. Use of such a model to investigate the impact of extending test intervals can result in large differences between the unavailabilities of components for which the test intervals differ significantly. Reviewers should be sensitive to this effect, and should ascertain that licensees use appropriate models and parameters for such evaluations.

As another example, in considering plant-specific failure data, poorly performing individual components may have been grouped with other components, allowing their poor performance to be averaged over all components of that type. Poor performance may arise because of inherent characteristics of one member of what would otherwise be considered a uniform population, or may arise because components are operating in a more demanding environment. If these components are grouped together with others for which the operating conditions are more favorable, the failure rates used for the poor performers could be artificially lowered. If requirements are relaxed on the basis of the group failure rate, reduced programmatic attention to these poor performers could lead to a greater-than-expected probability of experiencing an inservice failure of one of these components. Reviewers should be aware of such effects, and should ensure that the components are grouped appropriately.

When the impact of the change is modeled as a change in the parameter values associated with specific basic events representing modes of unavailability of SSCs, reviewers should focus on whether the change in parameter values is appropriate and reasonable. The licensee is expected to document the rationale behind the change in parameter values, and that rationale should be carefully reviewed.

If generic values are used for the base case parameter values which are candidates for change, reviewers should verify that the conditions under which the generic data apply do not correspond to those which would be more appropriate for a plant with the change incorporated. This should only be a real concern if the plant being changed is somewhat atypical with respect to the issue being addressed by the change. This would not be a concern if plant-specific data were used.

Finally, to validate the data used to justify changes in risk-informed applications, it is important for licensees to monitor the performance of components affected by the application. This monitoring should be performed as the proposed application is phased in. For very reliable SSCs, it may be necessary for the licensee to review available operating experience at other plants for applicability to the licensee's plant to expand the operating experience database. Reviewers should ascertain that the monitoring program is capable of demonstrating that the performance of the components or systems is in accordance with what has been assumed.

c. Evaluation Findings

Reviewers should verify that information provided and review activities conducted support the following conclusions:

- The failure rates and probabilities used, especially those that directly affect the proposed application, appropriately consider both plant-specific and generic data that are consistent with generally accepted values from PRAs of similar plants, and deviations (if any) have been justified on the basis of plant-specific factors.

- The licensee has systematically considered the possibility that individual components could be performing more poorly than the average associated with their class, and has avoided relaxation for those components to the point where the unavailability of the poor performers would be appreciably worse than that assumed in the risk analysis.

- The changes to the parameter values impacted by the application are both justified and reasonable.

- Data used to support changes to the plant's design or operations are supported by an appropriate performance monitoring program.

A.7 Modeling of Common Cause Failures

a. Areas of Review

Common cause failures (CCFs) represent the failures of components that are caused by common influences such as design, manufacturing, installation, calibration, or operational deficiencies. Since CCFs can fail more than one component at the same time and can occur with greater probability than would be predicted by the product of the individual component failure probabilities, they can significantly contribute to plant risk.

Risk-informed applications that cover SSCs as a group have the potential to affect the CCF probabilities of SSCs within the given group. For the affected components, CCF probabilities could be low or might not even be included in the baseline PRA models based on the operational and engineering evidence driven by current requirements. With proposed changes, there should be assurance that the CCF contribution will not become more significant. In addition, the assessment of the impact of the change can be affected by the CCF probabilities for other components, and can either be exaggerated or obscured depending on the CCF probabilities.

b. Review Guidance and Procedures

Reviewers should verify that the PRA addressed potentially significant CCFs and that, where applicable, the CCF modeling has incorporated the effects of the proposed changes. Staff evaluation should include a review of the process used to select common cause component groups.

Specific review guidelines related to risk-informed applications and the assessment of the change are as follows:

- Reviewers should verify that industry and especially plant-specific experience involving the failure of two or more components (especially for the application-specific components) from the same cause was analyzed and incorporated into the risk model where appropriate.

- For relevant applications, reviewers should check that licensees have appropriately modeled the CCF of groups of equipment that were proposed for the change. In cases where the effects of the application on CCF cannot be easily evaluated or quantified, reviewers should establish that performance monitoring is capable of detecting CCF before multiple failures are likely to occur subsequent to an actual system challenge. In addition, to reduce fault exposure times for potential common cause failures, phased or incremental implementation should be considered as part of the effort to protect against CCF.

- Reviewers should ensure that the impact of the change is not inappropriately made insignificant by the choice of CCF probabilities for SSCs unaffected by the change. This can occur in two ways. First, the cutsets or scenarios containing events which represent failures of SSCs affected by the change may include CCF contributions from other SSCs which are too small. Second, the contribution of cutsets or scenarios which do not contain affected SSCs may be artificially increased by having CCF contributions that are too large so that the impact of the change is obscured. These cases will impact applications involving risk categorization by lowering the relative contribution (and importances) of the affected SSCs. An understanding of these effects can be obtained from sensitivity analyses performed by removing the pertinent CCFs or by using more realistic values for the CCFs.

- A common modeling approximation is to include CCF contributions only from that combination of SSCs which fails the function of the system. For example, if system success is defined as success of one out of four components, usually only a single term representing a CCF of all four components is included. If the success criterion were two out of four, the corresponding CCF term would represent failure of any three or all four SSCs in the group. While probabilistically this usually corresponds to the dominant contributions, care has to be taken when the application relies on assessing the impact on risk of having one train unavailable. In this case, the effective success criterion of the remaining part of the system changes, so that in the case of the one-out-of-four system, a CCF of three SSCs becomes a possible contributor. The impact of not modeling the lower-order CCF contributors should be investigated. Note that this can impact applications for which the justification of the change relies on risk categorization, as well as those that require an evaluation of changes to risk.

c. Evaluation Findings

Evaluation findings should include statements to the following effect:

- Common cause failure has been suitably addressed, and the licensee has systematically identified component groups sharing attributes that correlate with CCF potential and that affect the application.

- Where applicable, the licensee's performance monitoring program addresses a phased implementation approach to reduce the potential for increased incidence of CCFs attributable to the proposed change.

A.8 Modeling of Human Performance

a. Areas of Review

The results of a PRA, and therefore the input it provides to risk-informed decisionmaking, can be very strongly influenced by the modeling of human performance. Plant safety depends significantly on human performance, so it is essential that the PRA treat it carefully. However, the modeling of human performance, typically referred to as human reliability analysis (HRA), is a relatively difficult area; significant variations in approach continue to be encountered, and these can yield significantly different estimates of human error probabilities (HEPs) for what appears to be similar human failure events. The particular values used for HEPs can significantly influence results of the assessment of the impact of a proposed change.

In addition to the quantification issue, there are questions related to what kind of human actions can appropriately be credited in the context of a particular regulatory finding. As an example, suppose that PRA results appear to support relaxation of requirements for a component based on the argument that even if the component fails, its failure can be recovered with high probability by operator actions outside the control room. The issues of concern here are whether the modeling of the operator action and the evaluation of the failure probability is appropriate, and whether this kind of credit is the sort of compensating measure that is intended by staff guidance to support justification of a relaxation. One further issue involves the impact of human performance which is not explicitly modeled, but is implicit in certain parameter values. An example is the influence of human performance on initiating event frequency. The causes of initiating events are typically not addressed; their impact is included in the frequency in an implicit way.

b. Review Guidance and Procedures

Reviewers should understand the potentially significant human performance issues that might be affected by the application and how these are reflected in the PRA. This understanding requires a review of the approach used to estimate human error probabilities.

The HRA can impact the assessment of the change in several ways. First, the change may directly affect the human failure events (HFEs). Second, the HFEs may represent responses to failures of the SSCs impacted by the change. Finally, HFEs unrelated to the change can obscure or exaggerate the impact of the change (depending on their values) by inappropriately increasing or decreasing the value of the accident sequences unaffected by the change.

When the change directly impacts the HFEs (e.g., as a result of a procedure change or a change in operating practice), reviewers should ensure that the licensee appropriately model the impact; that is reviewers should ensure that the licensee addressed the following questions:

- whether new human actions are introduced or whether existing actions are modified or eliminated

- whether the change affects factors assumed to impact the likelihood of failure (usually called performance shaping factors or PSFs), including: the quality of the procedures; the cues available to the operators; the quality of the information (instrumentation) available to the operators; the quality of the human-machine interface; the location of the interface(s); the complexity of the task; the conditions or context within which the operators are responding, including previous failures, previous actions, etc.; the time available to perform the task; the quality of the training (type and frequency) on the specific event; the crew interactions and the potential for recovery from errors; and the stress on the operators

- whether the human action dependency analysis is affected

- whether the application introduces or modifies dependencies between plant instrumentation and human actions

- whether the screening analysis is affected

When HFEs represent responses to failures of the SSCs impacted by the change, reviewers may want to focus their resources on these HFEs in the following ways:

- Identify any human actions that compensate for events affected by the proposed application, and ensure that the licensee did not claim inappropriate credit for these events. For human actions that are used to compensate for a basic event probability increasing as a result of proposed changes, licensee actions to ensure operator performance at the level credited in the risk analysis should also be a part of the change request.

- Ensure that appropriate justification is provided when the licensee takes credit for post-accident recovery of failed components (repair or other non-proceduralized manual actions, such as manually forcing stuck valves to open). Reviewers should also ascertain whether the identified recovery action is an obvious, feasible (given the time and physical constraints), and supportable by plant programs such as training.

- Ensure that the licensee assessed whether the conditions under which the human actions are to be performed have changed significantly so that the HEP should be modified.

Reviewers should also be aware that the impact of the change can be obscured if the accident sequences which do not contain affected SSCs are artificially increased in value by HEPs that are too large. These cases will impact applications involving risk categorization by lowering the relative contribution of the affected SSCs. An understanding of these effects can be obtained from sensitivity analyses performed by removing the pertinent HEPs or by using more realistic values for the HEPs.

Another consideration associated with the potential masking of important SSCs is that the SSCs might not be included in the model used to perform the evaluation of risk. This can happen in several ways:

- Cutsets or scenarios containing the SSCs may be truncated because HEPs in the same cutset or scenario are too low. Such truncation should only be a concern if the logic model was not re-solved to determine the change in risk (for example, in applications that depend on SSC risk ranking using a pre-solved equation). The preferred resolution to this would be a request for re-solution with the appropriate changes made to all affected SSCs. Section A.9 of this SRP chapter discusses this in more detail.

- SSCs may not be included in the logic model structure because HEPs are so high that they are assumed to dominate the unavailability of a function, and therefore the associated hardware is not modeled. However, the hardware could still be a contributor to the calculation of risk importance. For example, the hardware (as a group) will have the same risk importance (in terms of Risk Achievement Worth) as the associated HFE. This suggests that the licensees should identify the important operator actions for applications in RIR, as well as the equipment required to perform the specific function associated with the action. The equipment should then be dispositioned in accordance with its importance in achieving that function.

- For some complex groups of operator actions (e.g., the response to an ATWS in a BWR, or the choice to go to recirculation rather than RHR in response to a small LOCA in a PWR), the PRA analysts may have chosen to adopt a bounding approach to the accident scenarios which precludes having to address subsequent actions. This could mean that the equipment associated with those actions might be overlooked in the change process.

c. Evaluation Findings

The staff safety evaluation report should include language equivalent in effect to the following:

- The modeling of human performance is appropriate.

- Post-accident recovery of failed components is modeled in a defensible way. Recovery probabilities are realistically quantified. The formulation of the model shows decisionmakers the degree to which the apparently low risk significance of certain items is dependent on credit for recovery of failed components (restoration of component function, as opposed to actuation of a compensating system).

- When human actions are proposed as compensatory measures as part of a proposed change, licensee actions to ensure operator performance at the level credited in the risk analysis (e.g., by training, procedures, etc.) are also a part of the change request.

A.9 <u>Sequence Quantification</u>

a. Areas of Review

The staff would not generally anticipate the need to perform a detailed review of the quantification of the change in risk; however, some details of the quantification process should be confirmed. Specifically, reviewers should be confident that the licensee's evaluation process is sufficient to account for the potential effects of the proposed change on modeling simplifications and assumptions made during the quantification of risk. In addition, the staff should ensure that the chosen sequence truncation limits are appropriate so that important sequences are not discarded and final results are not sensitive to the chosen truncation limit.

b. Review Guidance and Procedures

Reviewers should verify that model simplifications and assumptions made during the quantification process are properly accounted for in evaluating of the change in risk, as illustrated by the following examples:

- Reviewers should ensure that the licensee accounted for model asymmetries during the application of the PRA models. Asymmetries could result from modeling assumptions (e.g., assuming one train to be the operating train, and the second train to be the standby train), from differences in support system alignment, or from actual differences in system design or operating procedures. The licensees should have accounted for these asymmetries when evaluating changes to the affected systems.

- Reviewers should ensure that, if cutset/sequence deletion is performed during quantification, these are correctly addressed in the assessment of risk change. In some quantification processes, cutsets that contain combinations of maintenance actions that are disallowed by the Technical Specifications are deleted from the accident sequence equations after the merging of functional cutset equations. This is done to avoid undue conservatism. If the PRA application deals with Technical Specification allowed outage issues, reviewers should confirm that any impacts on such deletions have been correctly addressed.

- Reviewers should ensure that, if operator recovery actions are incorporated after the initial quantification, these actions are still valid in light of the proposed change. Section A.8 of this SRP chapter discusses this in more detail.

- Circular logic in fault trees will cause the quantification process to abort. This is a problem for systems such as the emergency service water system, which provides cooling to the emergency diesel generators, but requires power from those diesel generators when offsite power is lost. Another example is the mutual dependency between the DC and AC power systems. In situations such as these (i.e., when the physical situation has embedded circular dependencies), analysts have to break this circularity to allow for model solution. For changes on systems that are affected by circular logic, reviewers should investigate the manner in which the circularity was broken (usually in the sequencing of functions in the event tree) and should verify that the dependency is still being accounted for in the evaluation of the risk change.

Sequence Truncation

The staff prefers that licensees calculate the change in risk from the application by requantifying the base PRA model so that the potential effects of originally truncated events can be accounted for should they become important as a result of an application. If the licensee did not requantify the model, or if the application depended on the risk ranking of SSCs from a pre-solved equation, reviewers should use the guidelines provided below.

Reviewers should be assured (either by documentation provided in the licensee's submittal or by an independent staff analysis) that cutset or scenario truncation did not introduce errors into the application results or the logic of the PRA that affects the application. Staff review could also involve performing (or reviewing) sensitivity studies where the truncation limit is lowered for the dominant sequences and event initiators, and studying the resultant cutsets or scenarios to see if there are any hidden dependencies or unusual/unexpected event combinations (especially if these involve components affected by the proposed application).

Staff review could also include comparing a list of the events affected by the application that is in the final truncated cutset equations to the list of application-specific basic events used in the fault tree and event tree models. This yields a list of events that did not make it pass the truncation process. Documentation should be available to enable reviewers to determine the reason truncated events are not important to risk.

Finally, in PRA models where common cause failures and human dependencies are incorporated at the sequence level after a truncated set of minimal cutsets has been obtained, reviewers should verify that the truncation criteria used in the PRA do not lead to cutsets involving application-specific components being truncated that could be important if common cause failures or human dependencies are considered.

c. Evaluation Findings

Reviewers should verify that the information provided and review activities conducted support the following conclusions:

- The change is appropriately modeled and is properly quantified.

- The licensee has satisfactorily established that conclusions are not adversely affected by truncation either because (i) the change in risk from the application was calculated by the requantification of the base model, or (ii) if model requantification was not performed, or if the application depended on the risk ranking of SSCs from a pre-solved cutset equation, the following apply:

    - The truncation criterion is sufficiently low to ensure stable results, that is, the magnitude of the CDF or release frequency will not change as a result of lower truncation limits, and the grouping of SSCs into risk categories will not be affected.

    - The components affected by the application are, for the most part, not truncated out of the model. In cases where they are, a qualitative assessment can demonstrate the reasons why they are unimportant to risk.

A.10 <u>Modeling of Containment Response and Changes in Large Early Release Frequency</u>

a. Areas of Review

The purpose of this section is to provide guidance for use in reviewing the licensee's evaluation of changes in LERF stemming from proposed changes to the plant's design or operations.

In general, only a subset of CDF sequences will be affected by a change. Whether or not this subset contributes significantly to LERF depends on several plant-specific characteristics. This section focuses on the characteristics that strongly affect LERF, and identifies review approaches based on these characteristics. It also provides guidance to help reviewers identify the major items related to functional plant capability that directly affect the potential for large early release; to direct reviewers in establishing whether the proposed changes can affect this capability; and to determine whether the licensee has appropriately addressed these items in estimating changes in LERF.

b. Review Guidance and Procedures

There are several ways in which a change to the plant's design or operation can significantly alter LERF, including those that:

- Change the frequency of containment bypass sequences (e.g., steam generator tube ruptures and interfacing system LOCAs).

- Change the frequency of core damage sequences that pose severe challenges to containment (e.g., sequences resulting in elevated reactor coolant system (RCS) pressure during core damage and at vessel failure).

- Change the performance of systems involved in containment safety functions (e.g., containment isolation, containment heat removal, containment sprays, hydrogen control, etc.).

- Change the performance of systems or operator actions that affect accident management strategies (e.g., depressurization, venting, etc.).

- Change the frequency of core damage sequences occurring at shutdown with containment functionality reduced.

The guidance provided below focuses, for each plant type, on particular examples of these general categories.

Based on previous PRAs, draft NUREG/CR-6595 developed some insights on the factors that most strongly affect the estimated likelihood of a large early release. Although plant-specific details may become significant in some cases, it was found that plants of each major containment type tend to be similar in the types of sequences that could lead to a large early release, reflecting strengths and weaknesses of that containment structure and particular features of the core damage sequences that characterize that plant type. Based on these insights, draft NUREG/CR-6595 presents a screening approach to evaluate the frequencies of dominant containment failure modes and bypass events. The purpose of this approach is to provide estimates of LERF, given certain characteristics of core damage sequences as input.

The review approach presented in this SRP section builds upon the underlying insights from draft NUREG/CR-6595. For each major containment type, particular considerations are suggested for attention in the review process. However, it is not intended to suggest that these considerations exhaust the technical issues that affect the potential for large early release. For example, where plant-specific PRA Level 2 analyses exist, these could provide further insights into LERF considerations for that plant.

For each major containment type, the factors that most strongly affect the potential for large early release (given that a core damage sequence is underway) are as follows:

PWR Large Dry:	Containment bypass Containment isolation RCS depressurization Emergency core cooling (ECC) restoration before vessel failure
PWR Ice Condenser:	Containment isolation Containment bypass Hydrogen igniters RCS depressurization ECC restoration before vessel failure
BWR Mark I and II:	Containment isolation Containment bypass Venting Containment heat removal: decay heat Containment heat removal: ATWS RCS depressurization ECC restoration before vessel failure
BWR Mark III:	All Mark I and Mark II issues Igniters

It should be noted that, at some BWRs, many sequences that result in vessel breach have a significant probability of also failing the containment. Also, the reader should note that a loss of containment heat removal may significantly contribute to CDF.

In reviewing the calculation of change in LERF for a given plant type, reviewers should consider the following factors:

Containment Bypass:

- Whether the proposed change affects systems that are credited in the prevention of, or in response to an initiating event involving a steam generator tube rupture (SGTR) or an ISLOCA.
- Whether the proposed change affects the frequency or severity of transients that could result in induced steam generator tube ruptures (ISGTR) (i.e., tube rupture in the course of an accident, caused by elevated temperatures and/or elevated pressure differentials). If the proposed change does not directly affect steam generator tube integrity, and the steam generators in the plant are not experiencing significant degradation, only a qualitative analysis may be needed to ensure that the risk of ISGTR is not significantly increased by the proposed change. However, if the plant has suffered a steam generator tube rupture, or has been shut down because of excessive steam generator tube leakage, or has detected tubes which do not meet applicable ASME Code requirements for structural integrity, or has repaired a significant amount of tubes as a result of free span degradation, the application should provide a more thorough analysis of the effects of the proposal on the risk associated with ISGTR.

Containment Isolation:

- Whether the proposed change affects systems that perform or support the isolation function.

- Whether the proposed change affects systems that prevent or mitigate core damage sequences initiated during periods of reduced containment functionality (e.g., shutdown).

- Whether the proposed change affects the ability to restore containment function during such periods (e.g., AC power, plant procedures, etc.).

Igniters:

- Whether the proposed change affects the igniters or any applicable support systems.

ECC Restoration Before Vessel Failure:

- If credit was taken in the estimate of LERF for recovery of cooling before vessel failure, whether the proposed change affects performance of any system thus credited (including support systems).

- Whether the proposed change affects other accident management strategies credited in the PRA (e.g., external vessel flooding).

RCS Pressure at Vessel Failure:

- Whether the proposed change affects the capability to depressurize the RCS.

Venting:

- Whether the proposed change affects the capability to vent the containment.

Containment Heat Removal:

- Whether the proposed change affects systems credited in containment heat removal (including front-line and support systems).

- Whether the proposed change affects the frequency or severity of ATWS sequences.

For each of the above considerations that apply, reviewers should ascertain that the licensee adequately evaluated the effects and took them into account in calculating the change in LERF.

c. Evaluation Findings

The safety evaluation report should contain findings equivalent to the following.

- The calculation for the change in LERF resulting from a proposed change has systematically taken into account the dominant causes of containment failure. In particular, the calculation has considered: bypass sequences; sequences posing relatively severe challenges to containment, or sequences occurring during periods of reduced containment functionality (shutdown); performance of systems involved in containment safety functions, including containment heat removal, sprays, isolation, and restoration of containment functionality (shutdown); and performance of systems involved in accident management strategies.

A.11 Bibliography

This section provides a list of documents of that the staff could use as reference or background material during the review process. This bibliography is divided into general categories in the areas of: desirable PRA attributes, review of the PRA, uncertainty and sensitivity analyses, and use of the PRA in risk ranking. In addition, a bibliography is provided for each of the review categories discussed in Sections A.1 through A.10 of this appendix.

General - Desirable PRA Attributes

Electric Power Research Institute, "PSA Applications Guide," EPRI TR-105396, August 1995.

Electric Power Research Institute, "Development of a Quality Pedigree Process and Application to the Duane Arnold Energy Center Probabilistic Safety Assessment," EPRI TR-106575, August 1996 (proprietary document - contact EPRI for availability).

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

USNRC, "A Review of NRC Staff Uses of Probabilistic Risk Assessment," NUREG-1489, March 1994.

USNRC, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," NUREG-1560, December 1997.

USNRC, "The Use of PRA in Risk-Informed Applications," (Draft for Comment) NUREG-1602, April 1997.

USNRC, "PRA Procedures Guide," NUREG/CR-2300, January 1983.

USNRC, "Probabilistic Safety Analysis Procedures Guide," NUREG/CR-2815, Rev. 1, August 1985.

USNRC, "Plan for Implementing Regulatory Review Group Recommendations," SECY-94-003, January 1994.

General - Review of the PRA

Boiling Water Reactor Owners' Group, "Report to the Industry on PSA Peer Review Certification Process: Pilot Plant Results," January 1997.

Electric Power Research Institute, "Individual Plant Examination Review Guide," EPRI TR-100369, February 1992.

International Atomic Energy Agency, "IPERS Guidelines for the International Peer Review Service," IAEA-TECDOC-832 Second edition, October 1995.

USNRC, "Individual Plant Examination: Submittal Guidance," NUREG-1335, August 1989.

USNRC, "Procedural and Submittal Guidance for the Individual Plant Examination of External Events (IPEEE) for Severe Accident Vulnerabilities," NUREG-1407, May 1991.

USNRC, "PRA Review Manual," NUREG/CR-3485, 1985.

General - PRA Uncertainties and Sensitivity Studies

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

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

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

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

Proceedings of Workshop I in Advanced Topics in Risk and Reliability Analysis, Model Uncertainty: Its Characterization and Quantification, held in Annapolis, Maryland, October 20-22, 1993, University of Maryland Press, 1996.

Special Issue on Treatment of Aleatory and Epistemic Uncertainty, Reliability Engineering and System Safety, Vol. 54, nos 2 and 3, November/December 1996.

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

USNRC, "Sensitivity Analysis Techniques: Self Teaching Curriculum," NUREG/CR-2350, June 1982.

USNRC, "Approaches to Uncertainty Analysis in Probabilistic Risk Assessment," NUREG/CR-4836, January 1988.

General - Use of PRA for Risk Ranking

USNRC, "Measures of Risk Importance and Their Applications," NUREG/CR-3385, July 1983.

Vesely, W.E., "The Use of Risk Importances for Risk-Based Applications and Risk-Based Regulation," in proceedings of PSA '96, Park City Utah, September 1996.

Initiating Events

Electric Power Research Institute, "ATWS--A Reappraisal, Part 3, Frequency of Anticipated Transients," EPRI NP-2330, 1982.

Nuclear Safety Analysis Center, "Loss of Offsite Power at U.S. Nuclear Power Plants Through 1991," NSAC-182, March 1992.

USNRC, "Evaluation of Station Blackout Accidents at Nuclear Power Plants," NUREG-1032, June 1988.

USNRC, "Development of Transient Initiating Event Frequencies for Use in Probabilistic Risk Assessments," NUREG/CR-3862, May 1985.

USNRC, "Modeling Time to Recovery and Initiating Event Frequency for Loss of Offsite Power Incidents at Nuclear Power Plants," NUREG/CR-5032, January 1988.

USNRC, "ISLOCA Research Program Final Report," NUREG/CR-5928, July 1993.

Accident Sequence Analysis (Event Trees)

USNRC, "PRA Procedures Guide," NUREG/CR-2300 Chapter 3.4, January 1983.

System Modeling Analysis (Fault Trees)

USNRC, "Fault Tree Handbook," NUREG-0492, January 1981.

USNRC, "PRA Procedures Guide," NUREG/CR-2300 Chapter 3.5, January 1983.

Dependent Failure Analysis

USNRC, "PRA Procedures Guide," NUREG/CR-2300 Chapter 3.7, January 1983.

Determination of Success Criteria

Brookhaven National Laboratory, "MAAP 3.0B Code Evaluation Final Report," FIN L-1499, October 1992.

Electric Power Research Institute, "MAAP Thermal-Hydraulic Quantification Studies," EPRI TR-100741, June 1992.

Electric Power Research Institute, "MAAP BWR Application Guidelines," EPRI TR-100742, June 1992.

Electric Power Research Institute, "MAAP PWR Application Guidelines for Westinghouse and Combustion Engineering Plants," EPRI TR-100741, June 1992.

Fauske & Associates, Inc., "MAAP 3.0B Users Manual," March 1990.

USNRC, "RELAP5/MOD3 Code Manual," NUREG/CR-5535 Volumes 1-5, June 1990.

USNRC, "TRAC-PF1/MOD2 Code Manual," NUREG/CR-5673 Volumes 1-4, 1994.

Westinghouse Electric Corporation, "Reactor Coolant Pump Seal Performance Following Loss of All AC Power," WCAP-10541, Revision 1.

Use of Appropriate Data

Electric Power Research Institute, "Nuclear Plant Reliability: Data Collection and Usage Guides," EPRI TR-100381, April 1992.

Idaho National Engineering Laboratory, "Emergency Diesel Generator Power System Reliability 1987-1993," INEL-95/0035, February 1996.

Institute of Electrical and Electronics Engineers, "Guide to the Selection and Presentation of Electrical, Electronic and Sensing Component Reliability Data for Nuclear Power Generating Stations," IEEE-STD-500 Rev. 1, 1984.

International Atomic Energy Agency, "Component Reliability Data for Use in Probabilistic Safety Assessment," IAEA-TECDOC-478, October 1988.

International Atomic Energy Agency, "Evaluation of Reliability Data Sources," IAEA-TECDOC-504, April 1989.

International Atomic Energy Agency, "Survey of Ranges of Component Reliability Data for Use in Probabilistic Safety Assessment," IAEA-TECDOC-508, June 1989.

T-Book, 3rd edition, "Reliability Data of Components in Nordic Nuclear Power Plants," published by ATV Office, Vattenfall AB, Sweden, 1992.

USNRC, "Data Summaries of Licensee Event Reports on Pumps at U.S. Commercial Nuclear Power Plants," NUREG/CR-1025 Rev. 1, 1982.

USNRC, "Data Summaries of Licensee Event Reports of Valves of U.S. Commercial Nuclear Power Plants," NUREG/CR-1363, 1982.

USNRC, "Data Summaries of Licensee Event Reports of Selected Instrumentation and Control Components at U.S. Commercial Nuclear Power Plants, January 1, 1976 to December 31 1981," NUREG/CR-1740, 1984.

USNRC, "Data Summaries of Licensee Event Reports of Inverters at U.S. Commercial Nuclear Power Plants, January 1, 1976 to December 31 1982," NUREG/CR-3867, 1984.

USNRC, "Data Summaries of Licensee Event Reports of Protective Relays and Circuit Breakers at U.S. Commercial Nuclear Power Plants, January 1 1976 to December 31 1983," Draft NUREG/CR-4126, 1985.

Modeling of Common Cause Failures

Idaho National Engineering Laboratory, "Common Cause Failure Data Collection and Analysis System," Draft INEL-94/0064, December 1995.

International Atomic Energy Agency, "Guidelines for Conducting Common Cause Failure Analysis in Probabilistic Risk Assessment," IAEA-TEC-DOC 648, 1992.

USNRC, "Procedures for Treating Common Cause Failures in Safety and Reliability Studies," NUREG/CR-4780 Volumes 1 & 2, January 1988.

Modeling of Human Performance

Chien, S.H., et. al., "Quantification of Human Error Rates Using SLIM-Based Approach," IEEE Fourth Conference on Human Factors and Power Plants, 1992.

Electric Power Research Institute, "Systematic Human Action Reliability Procedure," EPRI NP-3583, June 1984.

Electric Power Research Institute, "Operator Reliability Experiments Using Power Plant Simulators," EPRI NP-6937 Volumes 1-3, July 1990 (proprietary document - contact EPRI for availability).

Electric Power Research Institute, "Human Cognitive Reliability Model for PRA analysis," draft EPRI RP-2170-3, December 1984.

Electric Power Research Institute, "An Approach to the Analysis of Operator Actions in Probabilistic Risk Assessment," EPRI TR-100259, June 1992 (proprietary document - contact EPRI for availability).

Electric Power Research Institute, "SHARP1 - A Review of Systematic Human Action Reliability Procedure," EPRI TR-101711, December 1992 (proprietary document - contact EPRI for availability).

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USNRC, "A Procedure for Conducting a Human Reliability Analysis for Nuclear Power Plants," NUREG/CR-2254, 1983.

USNRC, "The Use of Performance Shaping Factors and Quantified Expert Judgement in the Evaluation of Human Reliability: An Initial Appraisal," NUREG/CR-2986, 1983.

USNRC, "SLIM/MAUD: An Approach to Assessing Human Error Probabilities Using Structured Expert Judgement," NUREG/CR-3518, Volumes 1&2, 1984.

USNRC, "Accident Sequence Evaluation Program - Human Reliability Analysis Procedure," NUREG/CR-4772, February 1987.

Sequence Quantification

Institute of Electrical and Electronics Engineers, "IEEE Standard for Software Verification and Validation Plans," IEEE Standard 1012-1986.

USNRC, "PRA Procedures Guide," NUREG/CR-2300 Chapter 6, January 1983.

USNRC, "Software Quality Assurance Program and Guidelines," NUREG/BR-0167, February 1993.

Modeling of Containment Response and Changes in Large Early Release Frequency

USNRC, "Risk Assessment of Severe Accident-Induced Steam Generator Tube Rupture," (Draft for Comment) NUREG-1570, May 1997.

USNRC, "Evaluation of Severe Accident Risks: Surry Unit 1," NUREG/CR-4551, Vol. 3, Rev. 1, Part 1, October 1990.

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USNRC, "Evaluation of Severe Accident Risks: Grand Gulf Unit 1," NUREG/CR-4551, Vol. 6, Rev. 1, Parts 1 and 2, December 1990.

USNRC, "Integrated Risk Assessment for the LaSalle Unit 2 Nuclear Power Plant: Phenomenology and Risk Uncertainty Evaluation Program (PRUEP)," NUREG/CR-5305, December 1990.

USNRC, "Evaluation of Severe Accident Risks: Zion Unit 1," NUREG/CR-4551, Vol. 7, Rev. 1, March 1993.

USNRC, "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," Draft NUREG/CR-6595, November 1997.

APPENDIX B

INTEGRATED DECISIONMAKING

Risk-informed applications are expected to require a process to integrate traditional engineering and probabilistic considerations to form the basis for acceptance. In order for this decisionmaking process to be effective in rendering accurate representations of plant safety and risk, the staff anticipates that licensees will have documented guidance to ensure consistent and defensible results. Such guidance would also allow staff reviewers to reconstruct the logic and events involved in the integration process.

This appendix discusses issues that the staff should address during reviews of the licensees' integrated decisionmaking process (sometimes referred to as the "expert panel" process).

a. Areas of Review

Staff reviewers are expected to evaluate proposed changes to the LB by taking into account both traditional and probabilistic engineering considerations. For each change, reviewers should evaluate the licensee's justification for the change and the process by which the results were obtained. In many pilot risk-informed applications, licensees have justified changes to the LB through the use of integrated decisionmaking panels (or expert panels) especially in cases where there are broad applications of PRA and traditional engineering results over a large number of plant elements (SSCs, operator actions, etc.). A review of the licensee's integrated decisionmaking process would ensure a better understanding of the reasons, assumptions, approaches, and information used to justify these changes.

b. Review Guidance and Procedures

Since the licensee's integrated decisionmaking process is responsible for justifying the acceptability of the proposed changes to the LB, the staff anticipates that licensees will document the process in a relatively formal fashion. The staff may not routinely audit all of the licensee's findings or recommendations, but the documentation should exist to support such a review, and should be maintained for the life of the plant or until such time at which the recommendations are invalidated by later changes.

Staff expectations of the integrated decisionmaking process

Reviewers should ensure that the licensee's decisionmaking process contains the following attributes:

- The process should be well-defined, systematic, repeatable, and scrutable. This process should be technically defensible and should be sufficiently detailed to allow an independent party to reproduce the major results.

- Deliberations should be application-specific. The objectives proposed for the integrated decisionmaking process for a particular application (particularly, how the results are to be utilized) should be well defined and relevant to the given application.

- Membership in the decisionmaking team should include experienced individuals with demonstrated skills and knowledge in relevant engineering disciplines (depending on the application), plant procedures and operations, plant systems (including operational history), system response and dependencies, operator training and response, details of the plant-specific PRA, and regulatory guidance.

- The decisionmaking team should have been advised of the specifics of all proposed changes and the relevant background information associated with the licensing action. In addition, since the judgement will depend, in part, on the results of a risk analysis, it is important that all team members be provided with an interpretation of the results of the risk model and the potential limitations of that model.

- The licensee's integrated decisionmaking process should take into account the principles and expectations described in Section II of this SRP chapter.

- In formulating the findings, the licensee should account for both probabilistic and traditional engineering considerations. This should include information from the risk analysis, traditional engineering evaluations and insights, quantitative sensitivity studies, operational experience and historical plant performance, engineering judgment, and current regulatory requirements. Potential limitations of the risk model should be identified and resolved. In addition, the licensee should individually consider and evaluate all SSCs that are affected by the proposed application but are not modeled in the PRA, on the basis of guidelines similar to those provided later in this appendix or in Section C.2 of Appendix C to this SRP chapter. Finally, the licensee's conclusions should be sufficiently robust with regard to different plausible assumptions and analyses.

- When findings or conclusions depend, in part, on the use of compensatory measures, the licensee should justify why the compensatory measures are an appropriate substitute for a proposed relaxation in current requirements. The compensatory measures should also become part of the plant's licensing basis.

Technical information basis for applications involving risk quantification or risk categorization

The staff expects that the information base supplied to the integrated decisionmaking panel will be capable of supporting the findings that should be made in the context of the specific risk-informed application. For example, in risk quantification and risk categorization applications, the following guidelines should be applicable.

- At least the Level 1 portion of the internal events PRA should be formulated in such a way as to support quantification of a change in risk (ΔCDF and ΔLERF) and importance measures, and should provide qualitative information (e.g., minimal cutsets) adequate to support defense-in-depth findings.

- There should be an inventory of plant response capability for probabilistically significant operating modes and initiating event categories (internal, external, flood, fire, seismic, etc.). Given a full-scope Level 2 PRA, this requirement could be satisfied by an inventory of event tree success paths, with an indication of the mission success criteria, systems, and SSCs involved in each path. Lacking a full-scope Level 2 PRA, surrogate information should be developed for unanalyzed areas, along the lines described in Section III.2.2.2 of this SRP chapter. This requirement is necessary in order to show the safety functions performed by SSCs (or other plant elements) affected by the application.

- Causal models (determination of cause-and-effect relationships) should be developed to support an evaluation (qualitative or quantitative) of the change in risk as a function of the application. This is necessary in order to relate the application to actual risk indices.

Documentation of inputs to the decisionmaking panel should be part of the process. Reviewers should verify the scope and depth of the information base, especially information supplied regarding modes and/or classes of initiators unanalyzed in the PRA.

Treatment of SSCs not modeled in the PRA

PRAs do not model all SSCs involved in performance of safety functions for various reasons. However, this should not imply that unmodeled SSCs are not important in terms of contributions to plant risk. For example, SSCs are omitted in some cases because the analysts take credit for programmatic activities that ensure a low failure frequency for that item or a short fault exposure time in the event that it does fail. In such cases, even though the PRA results will not reflect the SSC at all, it would be inappropriate to conclude that the programmatic activity is unimportant.

Consequently, one task of the integrated decisionmaking panel is to extrapolate from the PRA and other information sources to draw conclusions about SSCs that are not modeled in the PRA. This does not mean that the panel is to impute to the PRA high-level results that were not generated in the analysis; however, it does mean that if a success path is modeled in the PRA, the panel is justified in reasoning that unmodeled SSCs in that path are relied upon. If items were screened from the PRA, the panel should be aware of the screening process, in order to avoid violating the basis for the screening.

For SSCs not modeled in the PRA, reviewers should verify that the decisionmaking panel has performed the following tasks:

- Review the PRA assumption base for instances in which initiators were screened out on the basis of credit for SSCs affected by the application.
- Review plant operating history for initiating events that might have been prevented by the proposed application.
- Review plant operating history for failures of mitigating system trains attributable to events that might have been prevented by the proposed application.
- Review accident sequence modeling for instances in which early termination of the analysis obscured challenges to affected SSCs that would normally come into play later than the termination point.

Possible dispositions of the above tasks include the following results:

- The item will not affect initiating event frequency or mitigating system performance under reasonably foreseeable circumstances, and the proposed change is warranted.
- Although unmodeled, the item already receives and will continue to receive programmatic attention commensurate with its significance. In cases where reduced commitments are proposed, adequate justification is provided for this reduction.
- The item does not currently receive sufficient programmatic attention, and may be subject to tighter controls.

Reviewers should verify that the safety significance of SSCs not modeled in the PRA (but affected by the proposed application) are appropriately characterized and justified.

Addressing limitations of the risk analysis

One objective of the integrated decisionmaking process is to overcome certain limitations of the PRA. However, this does not include substituting the analyst's judgment for essential PRA results. One reason for developing PRA models is that the complexity of many facilities makes judgment difficult in many contexts.

Generally, if the PRA highlights a plant vulnerability, this should be taken seriously and should not be discounted on the basis of judgment. If the analyst can show that the PRA representation of a vulnerability is invalid, then the PRA should be modified, and the licensee should work with the results of the revised PRA.

To address the issue of credit for unmodeled systems that would change a PRA result, the preferred method is to alter the PRA to take the credit. Reviewers should be aware that cases may potentially arise in which credit for an unmodeled system would be seriously complicated by issues of shared support systems, environmental conditions, or other factors such as spatial interaction issues or operator interaction dependencies.

To address the issue of making decisions about SSCs that might influence plant response in unmodeled modes or to unmodeled initiators, the acceptable approach is to proceed on the basis of a structured representation of plant response that shows at least qualitatively the initiating events that may pertain, the systems available to respond to each, the functional dependencies of these systems, and the backups available in the event of failure of any particular SSC. While it is possible to accept program reductions for SSCs that are explicitly shown to play no role in unanalyzed modes, it is more difficult to accept reductions for components that do play a role in unanalyzed (e.g., shutdown) modes. For such instances, conservative methods will be considered prudent.

To address instances in which a PRA model exists but is considered misleading, caution is indicated. An example would be to down-classify SSCs from a PRA result (i.e., state that a high risk contributor is actually a low contributor), on the basis of panel judgment. It is not acceptable to place on the record both a PRA and a finding that clearly contradicts it. Although the panel is not expected to take the PRA as absolute truth, the test should be whether the record establishes a clear basis for a finding. A technical argument that begins with the misleading PRA result and furnishes supplementary information sufficient to justify a relatively minor change to a PRA result, or a qualified interpretation of a PRA result, is satisfactory. A cursory technical argument leading to a conclusion that qualitatively contradicts a major PRA result is an unsatisfactory record.

C. Evaluation Findings

The following language (or language equivalent to this) should appear in the SER, or exceptions should be noted and explained:

- The integrated decisionmaking process is appropriate. Appropriate information was available, suitable issues were raised, the disposition of these issues was systematic and defensible, and the documentation of the findings is traceable and reviewable in principle, so that the basis for conclusions and recommendations is available for scrutiny and review.
- The evaluation of risk significance represents appropriate consideration of probabilistic information, traditional engineering evaluations, sensitivity studies, operational experience, engineering judgment, and current regulatory requirements.

- The technical information basis was adequate for the scope of the application. In particular, the analysis of success and failure scenarios was adequate to identify the roles played by the SSCs affected by the application, the quantification of the frequency of these scenarios was adequate to establish the safety significance of the SSCs, and the causal models were adequate to establish the effects of the proposed changes in the program.

- The safety significance of components affected by the proposed application but not modeled in the PRA was evaluated in a systematic manner. This included a search of components that might contribute to initiating event occurrence, mitigating system components that were not modeled in the PRA because their failure was not expected to dominate system failure in the baseline configuration, and components in systems that do not play a direct role in accident mitigation but do interface with accident mitigating systems.

- The process applied by the licensee to overcome limitations of PRA was appropriate. Where decisions were made that do not follow straightforwardly from the PRA, a technical basis was provided that shows how the PRA information and the supplementary information validly combine to support the finding. No findings contradict the PRA in a fundamental way.

APPENDIX C

CATEGORIZATION OF PLANT ELEMENTS WITH RESPECT TO SAFETY SIGNIFICANCE

For several proposed applications in risk-informed regulation, one of the principal activities is the categorization of SSCs and human actions with respect to their safety-significance. This appendix discusses how to review approaches that may be used in this categorization process.

The first review consideration is the definition of safety-significance as it applies to SSCs and human actions for a specific application. A related, but not identical concept, is that of risk significance. For example, an individual SSC can be identified as being risk-significant if it can be demonstrated that its failure or unavailability contributes significantly to the measures of risk (e.g., CDF and LERF). Safety significance, on the other hand, can be thought of as being related to the role the SSC or human action plays in preventing the occurrence of the undesired end state. Thus, the SSCs and human actions considered when constructing the PRA model have the potential to be safety significant, since they play a role in preventing core damage or large early release. These SSCs and human actions may include those that do not necessarily appear in the final quantified model because they have initially been screened, are assumed to be inherently reliable, or have been truncated from the solution of the model. In addition, there may be SSCs or human actions not modeled in the PRA that have the potential to be safety significant because they play a role in preventing core damage or large early release.

In reviewing the categorization, it is important to recognize its underlying purpose. Categorization is generally intended to sort the SSCs or human actions into two general groups; those for which some change is proposed, and those for which no change is proposed. It is the potential impact of the application on the particular SSCs and human actions and on the measures of risk which ultimately determines which SSCs and human actions should be regarded as safety-significant. Since different applications impact different SSCs and human actions, it is reasonable to expect that the categorization could be different for different applications. Thus, the question being addressed by the application is, for which groups of SSCs and human actions can the change be made such that there will be no more than an insignificant increase in the risk to the health and safety of the public. This impact on overall risk should be related back to the criteria for acceptable changes in the risk measures identified in RG 1.174. It is those groups for which changes can be made that satisfy these criteria that can be regarded as low safety-significant in the context of the specific application. 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 for those applications for which a method for evaluating the impact of the change on SSC unavailability is not obviously available.

In such instances, an acceptable alternative to requantification of risk is to categorize SSCs and human actions using an integrated decisionmaking process (such as the use of an Expert Panel), with PRA importance measures as input. This appendix discusses the issues that reviewers should address for this approach. Section C.1 discusses the technical issues associated with the use of PRA importance measures, and Section C.2 discusses the use of the importance measures by the decisionmaking panel.

C.1 <u>Use of Importance Measures</u>

a. Areas of Review

In the implementation of the Maintenance Rule and in many industry guides for the risk-informed applications, the measures most commonly identified for use in the relative risk ranking of SSCs and human actions include the Fussell-Vesely Importance, Risk Reduction Worth, and Risk

Achievement Worth. However, in using of these importance measures for risk-informed applications, several issues should be addressed. Most of these issues relate to technical problems that can be resolved through the use of sensitivity studies or appropriate quantification techniques, as discussed in detail later in this section. In addition, there are two issues that reviewers should ensure have been adequately addressed, namely i) that risk rankings apply only to individual contributions and not to combinations or sets of contributors, and ii) that risk rankings are not necessarily related to the risk changes which result from those contributor changes. When correctly applied and interpreted, component-level importance measures can provide valuable input to the integrated decisionmaking process.

b. Review Guidance and Procedures

Risk ranking results from a PRA can be affected by many factors, the most important being the model assumptions and techniques (e.g., for modeling of human reliability or common cause failures), the data used, or the success criteria chosen. Reviewers should therefore evaluate the licensee's PRA as part of the overall review process. Appendix A to this SRP chapter presents guidance for this review.

In addition to using a PRA of appropriate quality for the application, the licensee should demonstrate the robustness of risk ranking results 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 integrated decisionmaking process should include sensitivity studies and/or other evaluations to demonstrate the sensitivity of the ranking results to the important PRA modeling techniques, assumptions, and data. In assessing this information, reviewers should consider the following issues:

Different risk metrics: Reviewers should ensure that the licensee's ranking process adequately considered risk in terms of both CDF and LERF.

Completeness of risk model: Reviewers should ensure that, when determining safety significance contributions using an internal events PRA, the licensee also considered external events, as well as shutdown and low-power initiators, either by PRA modeling or by the integrated decisionmaking process (as detailed in Section C.2 and Appendix B to this SRP chapter).

Sensitivity analysis for component data uncertainties: The licensee should have addressed the sensitivity of component categorizations to uncertainties in the parameter values. Reviewers 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. As discussed in Appendix A to this SRP chapter, CCF probabilities can impact PRA results by enhancing or obscuring the importance of components. This should be addressed by the review. 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. In RIR, removing or relaxing requirements may increase the CCF contribution, thereby changing the risk impact of an SSC.

Consideration of multiple failure modes: PRA basic events represent specific failure events and failure modes of SSCs. Reviewers should verify that the licensee performed the categorization by taking into account the combined effects of all associated basic PRA events (such as failure to start and failure to run), including indirect contributions through associated CCF event probabilities.

Sensitivity analysis for recovery actions: PRAs typically model recovery actions especially for dominant accident sequences. Quantification of recovery actions typically depends on the time available to diagnose the situation and perform the action, as well as the adequacy of the licensee's training, procedures, and operator knowledge. Estimating the success probability for the recovery actions involves a certain degree of subjectivity. The concerns in this case stem from situations where 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 impacted by recovery actions that sometimes are only modeled for the dominant scenarios. Sensitivity analyses can be used to show how the SSC categorization would change if recovery actions were removed. Reviewers should ensure that the categorization has not been unduly impacted by the modeling of recovery actions.

Truncation limit: Reviewers should verify that the licensee set the sequence truncation limits low enough so that the truncated set of minimal cutsets or scenarios contains the significant contributors and their logical combinations for the application in question. Depending on the level of PRA detail (module level, component level, or piece-part level), this may translate into a truncation limit from 10^{-12} to 10^{-8} per reactor year.

Multiple component considerations: As previously discussed, importance measures are typically evaluated on the basis of individual SSCs or human actions. One potential concern that arises from this practice is that single-event importance measures have the potential to dismiss all elements of a system or group, despite the system or group having 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.) Two potential approaches are used to address 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, it is likely that some licensees will develop new system or group measures. If any are proposed, reviewers should ensure that the measures logically capture the impact of changes to the group. As an example of the issues that arise, consider the following. For front-line systems, one possibility would be to define a Fussell-Vesely type measure of system importance as the sum of the frequencies of sequences involving failure of that system, divided by the sum of all sequence frequencies. Such a measure would need to be carefully interpreted if the numerator included contributions from failures of that system as a result of 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, the support systems again make the situation more complex. To take a two-division plant as an example, front-line failures can occur as a result of failure of support division A in conjunction with failure of front-line division B. Working with a figure of merit determined by the "total failure of support system" would miss contributions of this type.

In the absence of appropriately defined group level importance measures, reliance should be made on the integrated decisionmaking process to make the appropriate determination (see Section C.2).

Relationship of importance measures to risk changes: Importance measures do not directly relate to changes in risk associated with implementation of a set of changes proposed in an application. 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 group level. Therefore, the criteria for categorization into low and high significance should be related to the acceptance guidelines 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, reviewers should determine how the choice of criteria relates to, and conforms with, the acceptance guidelines described in RG 1.174. If component level criteria are used, they should be established taking into account the fact that the allowable risk increase associated with the change should be determined on the basis of simultaneous changes to all members of the category.

c. Evaluation Findings

The SER should incorporate language equivalent to the following, and exceptions (if any) should be noted and explained.

- The information provided to the integrated decisionmaking process with regard to determining the risk importance of contributors for a specific application is robust in terms of model inputs and assumptions including issues like the use of the use of both CDF and LERF, completeness of the risk model, and sensitivity of the results to data uncertainties, common cause failure modeling, modeling of human reliability, and truncation limits used.

- The categorization addresses the effect of the change on groups of components in a way that is compatible with the risk acceptance guidelines.

C.2 Role of Integrated Decisionmaking in Component Categorization

a. Areas of Review

While probabilistic importance analysis can provide valuable information regarding categorization of SSCs or human actions, it should be supported and supplemented by an evaluation based on traditional engineering considerations. This will require using the qualitative insights obtained from the PRA, and considering the maintenance of the defense-in-depth philosophy and sufficient safety margins. One important element of this integrated decisionmaking can be the use of an "expert panel." This section provides guidelines for reviewing the licensee's integrated decisionmaking process in the area of importance categorization, and it supplements the general guidance in Appendix B to this SRP chapter.

b. Review Guidance and Procedures

Identification of functions, systems, and components important to safety: The PRA can provide significant qualitative insights that emerge simply from considering whether and how systems are invoked in particular scenarios. If a front-line system is credited in success paths, it is "important" in some sense, and at least some of its SSCs must also be important in some sense, even if a given single-event importance measure does not reflect this. However, the real importance of a system is a function of whether alternative, diverse systems that could fulfill the same function. Those systems which are the only means of providing the function would be considered more important than those for which there are viable alternatives. A system that supports an important front-line system could also be considered important. This does not mean that all such systems cannot be candidates for relaxing current requirements; however, it does mean that components in system trains credited in the PRA should be explicitly considered during the integrated decisionmaking process.

Either by evaluating the licensee's documentation or by conducting an independent verification, reviewers should complete the following steps:

- Identify all systems that are relied upon in plant response to an initiating event, whether explicitly modeled in the PRA or not (e.g., room cooling systems, and instrumentation and control systems associated with indications rather than control may not be modeled), and identify the function(s) they perform or support.

- Determine whether failure of components screened out on the basis that they are elements of "unimportant" systems could affect a system that is relied upon in the plant's response to an initiating event.

Reviewers should then verify that at least some elements of each of the important systems identified above are considered "safety significant." If this is not the case, reviewers should ascertain what performance is allocated to these items in the PRA, and whether the programmatic activities allocated to these elements are commensurate with the given performance level. If a system is identified as being important, but none of its elements is, reviewers should carefully evaluate the licensee's justification.

As an example, consider the case of a system that contains many redundant flowpaths. Single-event importance analysis will tend to dismiss the flowpaths one at a time, effectively dismissing the group as a whole. The focus of the above guidance is that the redundant flowpaths (considered as a subsystem, and recognizing the function they perform), are important and deserve some attention, even though conventional importance measures would not highlight them. However, in the case of redundant systems, the solution need not always be to assign every redundant path to the high-risk contributor category. In this example, especially if the paths are essentially similar, it is arguably necessary to consider common cause failure. Thus, a program that addresses common cause failure potential by monitoring component performance may provide the necessary protection against loss of the function, while still allowing a decrease in some level of commitment on the individual members of the group.

Verification of low safety significance: In evaluating the qualitative risk-informed categorization, reviewers should consider the integrated decisionmaking process and criteria used by the licensee.

In reviews of the licensee's determination of low safety significance for SSCs or operator actions, reviewers should verify that the licensee appropriately applied risk importance measures and accounted for the results of sensitivity studies. Reviewers should also verify that the licensee considered and compensated for factors such as potential inadequate scope and level of detail of the PRA (see Sections III.2.2.2 and III.2.2.3 of this SRP chapter). Finally, reviewers should verify that, in categorizing an SSC or operator action as low safety significance, the licensee considered the defense-in-depth philosophy and available safety margins. Section III.2.1 of this SRP chapter presents review guidance on these topics.

For SSCs not modeled in the PRA, reviewers should verify that the licensee's process determined that the following conditions apply for each SSC that has been proposed as a candidate for relaxation or removal of current requirements:

- The SSC does not perform a safety function, or does not perform a support function to a safety function, or does not complement a safety function.

- The SSC does not support operator actions credited in PRAs for either procedural or recovery actions.

- The failure of the SSC will not result in the eventual occurrence of a PRA initiating event.

- The SSC is not a part of a system that acts as a barrier to fission product release during severe accidents.

- The failure of the SSC will not result in unintentional releases of radioactive material even in the absence of severe accident conditions.

If any of the above conditions apply, or if SSC performance is difficult to quantify, the licensee should have used a qualitative evaluation process to determine the impact of relaxing requirements on equipment reliability and performance. This evaluation should include identifying those failure modes for which the failure rate may increase, and those for which detection could become more difficult. Reviewers should then verify that the licensee provided one or more of the following (or similar) justifications:

- a qualitative discussion on how the change is consistent with the defense-in-depth philosophy and how the change maintains sufficient safety margins

- a qualitative discussion and historical evidence why these failure modes may be unlikely to occur

- a qualitative engineering discussion on how such failure modes could be detected in a timely fashion

- a discussion on what other requirements may be useful to control such failure rate increases

- a qualitative engineering discussion on why relaxing the requirements may have minimal impact on the failure rate increase

c. Evaluation Findings

The SER should incorporate language equivalent to the following, and exceptions (if any) should be noted and explained:

- The categorization of the SSCs or human actions has adequately captured their significance to safety, and has been performed in such a way that the potential impact of the proposed application results in at most a small increase in the risk to the health and safety of the public. The input to the integrated decisionmaking process derived from importance measures has been utilized, taking into account the known limitations of importance calculations, and the results have been supplemented by appropriate qualitative considerations.

- The integrated decisionmaking process explicitly recognized systems invoked in plant response to initiating events, and ensured that components within these systems are considered for programmatic attention in areas (IST, ISI, etc.) appropriate to their performance characteristics and the level of performance needed from them.

APPENDIX D

USE OF RISK INFORMATION IN REVIEW OF NON-RISK-INFORMED LICENSE AMENDMENT REQUESTS

Areas of Review

When a license amendment request complies with the regulations and other license requirements, there is a presumption by the Commission of adequate protection of public health and safety (Maine Yankee, ALAB-161, 6 AEC 1003 (1973)). However, circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as identification of an issue that substantially increases risk. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety. Section 182.a of the Atomic Energy Act of 1954, as amended, and as implemented by 10 CFR 2.102 gives the NRC the authority to require the submittal of information in connection with a license amendment request if NRC has reason to question adequate protection of public health and safety. The licensee may decline to submit such information, but it would risk having the amendment request denied if NRC cannot find that the requested amendment provides adequate protection of public health and safety.

Under unusual circumstances that could introduce significant and unanticipated risks, the NRC staff reviewers would assume the burden of demonstrating that the presumption of adequate protection is not supported by the bases for the existing staff positions despite the fact that currently specified regulatory requirements are met. Instances in which license amendment requests meet all regulatory requirements yet raise significant risk concerns are rare. The process used for identifying those situations in which risk implications are appropriate to consider and for deciding if undue risk exists is depicted in Figure 1. This process can be used in the review of both licensee-initiated, risk-informed license amendment requests, as well as license amendment requests in which the licensee chooses to not submit risk information (i.e., non-risk-informed requests).

License amendment requests will be screened for potential risk implications as part of the license amendment review process. Office-level license amendment review procedures provide guidance on which license amendment requests should be examined at the level of the integrated risk model because of the potential for significant impacts on plant risk. In accordance with the guidance, the risk implications of a non-risk-informed submittal would be discussed with a risk analyst if the submittal --

- significantly changes the allowed outage time (e.g., outside the range previously approved at similar plants), the probability of the initiating event, the probability of successful mitigative action, the functional recovery time, or the operator action requirement;

- significantly changes functional requirements or redundancy;

- significantly changes operations that affect the likelihood of undiscovered failures;

- significantly affects the basis for successful safety function; or

- could create “special circumstances” under which compliance with existing regulations may not produce the intended or expected level of safety and plant operation may pose an undue risk to public health and safety.

Non-risk-informed license amendment requests judged to have the potential to significantly affect risk would be referred for a more detailed risk evaluation as part of the license amendment review.

Review Guidance and Procedures

For license amendment requests referred for a risk review, the reviewers should assess the requested changes, and the need for and the effectiveness of any compensatory measures that might be warranted because of risk considerations, by evaluating the changes relative to the safety principles and integrated decisionmaking process defined in Regulatory Guide (RG) 1.174. The risk acceptance guidelines (Sections 2.2.4 and 2.2.5 of RG 1.174) describe acceptable levels of risk increase as a function of total core damage frequency (CDF) and large early release frequency (LERF) and the manner in which the acceptance guidelines should be applied in the review and decisionmaking process. Reviewers should note that the guidelines serve as a point of reference for gauging risk impact but are not legally binding requirements.

For non-risk-informed license amendment requests, the preliminary assessment would be qualitative, with a decision based on engineering judgment, since quantitative risk information would not generally be presented in submittals that are not risk informed. If "special circumstances" are believed to exist, the reviewers will explore in more detail the underlying engineering issues contributing to the risk concern, and the potential risk significance of the license amendment request. The staff should inform and engage the licensee as early as possible in the evaluation process when it believes that a special circumstance may exist and is considering the need for risk information.

"Special circumstances" represent conditions or situations that would raise questions about whether there is adequate protection and that could rebut the normal presumption of adequate protection from compliance with existing requirements. In such situations, undue risk may exist even when all regulatory requirements are satisfied. In general, a special circumstance may exist if (1) the situation was not identified or specifically addressed in the development of the current set of regulations and could be important enough to warrant a new regulation (e.g., a risk-informed regulation) if such situations were encountered on a widespread basis and (2) the reviewer has knowledge that the risk impact is not reflected by the licensing basis analysis and has reason to believe that the risk increase would warrant denial or attaching conditions to the staff's approval if the request were evaluated as a risk-informed application. If one criterion is met, the second would generally be met as well. However, in view of the judgment involved in these determinations, cases in which one of the criteria is not clearly met should still be elevated for management consideration as discussed below.

"Special circumstances" may include but not be limited to license amendment requests that, if approved, could --

! substantially increase the likelihood or consequences of accidents that are risk significant but are beyond the design and licensing basis of the plant, for example, proposed changes to steam generator (SG) allowable leak rates that meet 10 CFR Part 100 limits based on the design basis source term but result in a large early release given a severe accident source term; or use of new materials for SG repairs that provide acceptable performance under normal and design basis accident conditions but a reduced capability to maintain SG tube integrity in high-temperature, severe accident scenarios.

! degrade multiple levels of defense, or cornerstones in the reactor oversight process, through plant operations or situations not explicitly considered in the development of the regulations, for example, advanced applications of digital instrumentation and controls in which the licensee does not address or comply with regulatory guidance concerning evaluation of defense in depth and diversity in digital instrumentation and control systems.

- significantly reduce the availability or reliability of structures, systems, or components that are risk significant but are not required by regulations, for example, amendment requests that as an unintended consequence compromise the effectiveness of the Mark I hardened wetwell vent system in protecting against containment overpressure failures in accidents beyond the design basis, or the diversity of the turbine-driven auxiliary feedwater pumps provided in response to NUREG-0737, Section II.E.1.1.

- involve changes for which the synergistic or cumulative effects could significantly impact risk, for example, power uprate requests that would increase operating power well beyond the levels approved in previous uprates and would introduce or substantially increase the frequency of risk-significant core damage sequences.

If, upon further consideration, it is believed that approval of the request would compromise the safety principles described in RG 1.174 and substantially increase risk relative to the risk acceptance guidelines contained in the regulatory guide, the reviewers should inform NRC management of the risk concerns and the need to further evaluate the risk associated with the request. In such instances, the reviewers, with management concurrence, should ask the licensee to address the safety principles and the numerical guidelines for acceptable risk increases contained in RG 1.174 in its submittal. The reviewers may alternatively ask the licensee to submit the information needed in order for the NRC staff to make an independent risk assessment.

The appropriate level of management involvement would depend on the nature and significance of the issue. In general, the decision regarding whether a license amendment request creates a special circumstance should, at a minimum, be supported by the division directors responsible for probabilistic safety assessment, the technical issue and the regulatory requirements in question, and licensing project management, as well as the Office of the General Counsel. Review by the Risk-Informed Licensing Panel (RILP) should be considered for this purpose. The need to elevate the issue to a higher management level or to inform the Commission should be specifically addressed by the RILP if a special circumstance is determined to exist. The RILP should ensure that the burden imposed on the licensee in responding to risk questions raised by the NRC is justified in view of the potential safety significance of the issue to be addressed in the requested information.

If a licensee does not choose to address risk, the reviewers should not issue the requested amendment until they have sufficiently assessed the risk implications to determine that there is reasonable assurance that the public health and safety will be adequately protected if the amendment request is approved. A licensee’s decision not to submit requested information could impede the staff’s review and could also prevent the reviewers from reaching a finding that there is reasonable assurance of adequate protection. A licensee’s failure to submit requested information could also be a basis for rejection pursuant to 10 CFR 2.108.

Evaluation Findings

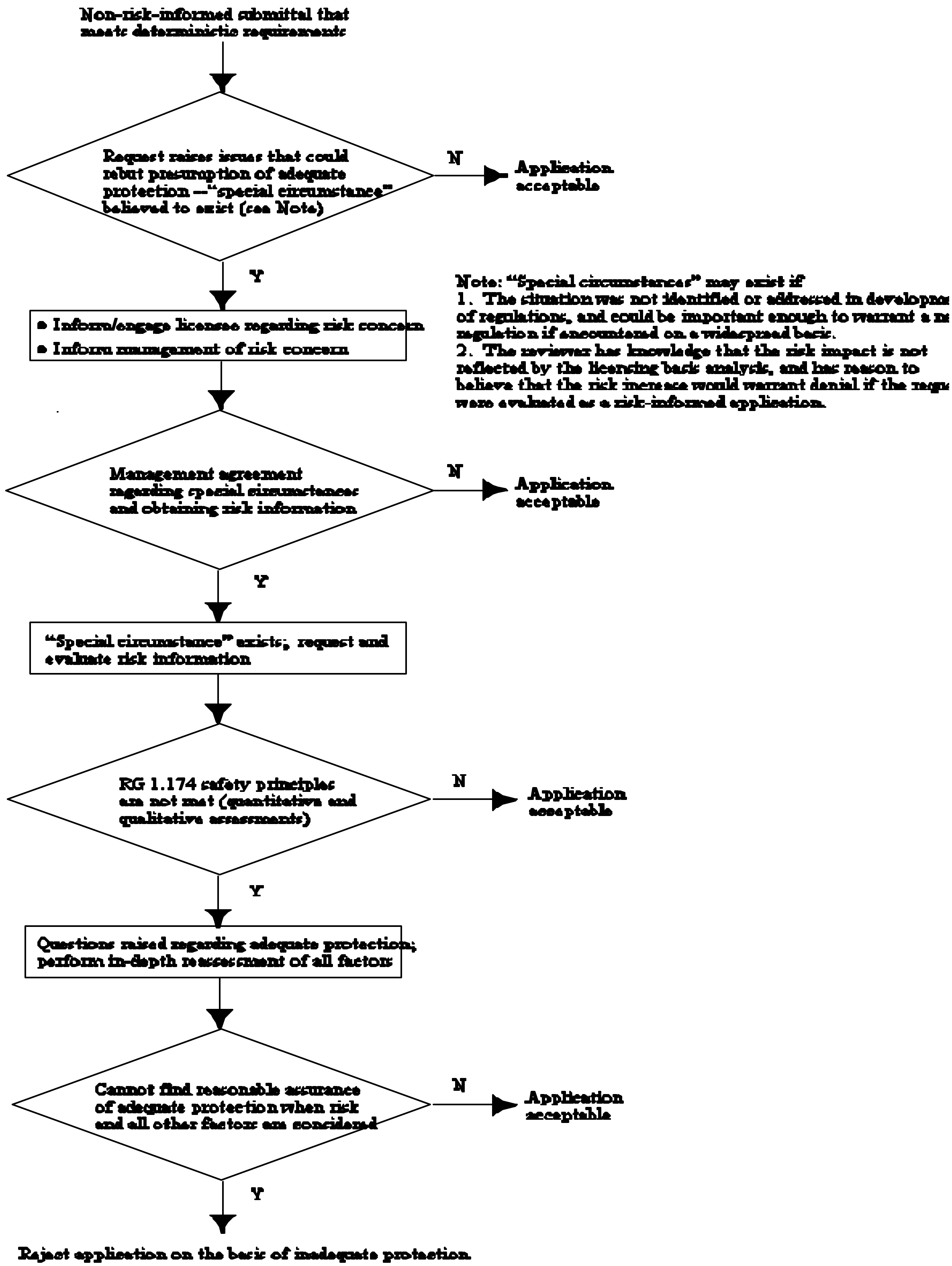
The numerical guidance for CDF and LERF and the safety principles provided in RG 1.174 are intended to provide a basis for finding that there is reasonable assurance of adequate protection. Therefore, situations that exceed these values or violate the other principles would constitute a trigger point at which questions are raised as to whether the proposed change provides reasonable assurance of adequate protection. A more in-depth assessment of the special circumstances, the safety principles, and the issues identified for management attention in

Section 2.2.6 of RG 1.174 should then be made in order to reach a conclusion regarding the level of safety associated with the requested change.

In making this assessment, the reviewers should be mindful to clearly differentiate the concept of adequate protection from the numerical risk acceptance guidelines. The guidelines in themselves do not constitute a definition of adequate protection but provide an appropriate set of criteria to be used in the process for evaluating adequate protection. As discussed in RG 1.174, the uncertainty in the analyses must be considered in any finding that adequate protection is achieved.

The final acceptability of the proposed change should be based on a consideration of current regulatory requirements, as well as on adherence to the safety principles, and not solely on the basis of a comparison of quantitative probabilistic risk assessment results with numerical acceptance guidelines. The decision to reject a non-risk-informed license amendment request on the basis of risk should be supported by the RILP and would be expected to be elevated to office-level management for a final decision. The authority provided by the Atomic Energy Act and current regulations requires rejection of a license amendment request if the NRC is unable to find that adequate protection is provided.

Figure 1 - Process and Logic for Considering Risk in License Amendment Reviews



Implementation Activity: **Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the appropriateness of PRA results used in support of regulatory applications.**

Primary Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The NRC is extensively using information from probabilistic risk assessments (PRAs) in its regulatory decision-making. To streamline staff review of licensee applications using risk insights, professional societies and the industry undertook the following initiatives for establishing consensus standards and guidance on the use of PRA in regulatory decision-making:

- The American Society of Mechanical Engineers (ASME) has developed a standard for a Level 1 analyses (i.e., estimation of core damage frequency (CDF)) and a simplified Level 2 analysis (i.e., estimation of large early release (LERF)) covering internal events (transients, loss of coolant accidents, and internal flood) at full power.
- The Nuclear Energy Institute (NEI) has developed a "PSA Peer Review Guidance,"
- (NEI-00-02) covering internal events at full power--Level 1 and simplified Level 2.
- The American Nuclear Society (ANS) is developing PRA standards for:
  - –external hazards with a tentative publication date of December 2002
  - –low power and shutdown with a tentative publication date of December 2003
  - –internal fires (with no date available at this time because ANS is in initial stages)

It is expected that licensees will use the PRA standards and industry guidance to help demonstrate and document the adequacy of their PRAs for a variety of risk-informed regulatory applications. Therefore, the staff should document its position on the appropriateness of the standards and industry guidance to support regulatory applications. Such documentation will indicate in which areas staff review can be minimized and where additional review may be expected. In order to accomplish this, the staff will publish a new regulatory guide (RG) providing an approach for assessing the adequacy of PRA results used in support of regulatory applications and an accompanying Standard Review Plan (SRP) chapter. The development of the RG will include consideration of recent guidance provided the staff by ACRS (March 19, 2002, memo to EDO) concerning the importance of late containment failure and inadvertent release of radioactive material.

The Regulatory Guide and associated SRP chapter are intended to support all risk informed activities. The main body of the RG will: (1) summarize Attachment 1 of the SECY-00-0162 and (2) provide advice on the use of PRA standards and industry guidance by licensees to determine the level of confidence that can be afforded PRA insights/results in support of decision-making. The staff's position on each PRA standard and industry guidance will be given in the appendices. For example, Appendix A will include the staff's position on the ASME standard and Appendix B on NEI-00-02. As noted in SECY-00-0162, the staff "may take exception to or include additional specific criteria to address any identified weaknesses in the standards to ensure that PRAs used in regulatory decision-making will have an adequate technical basis."

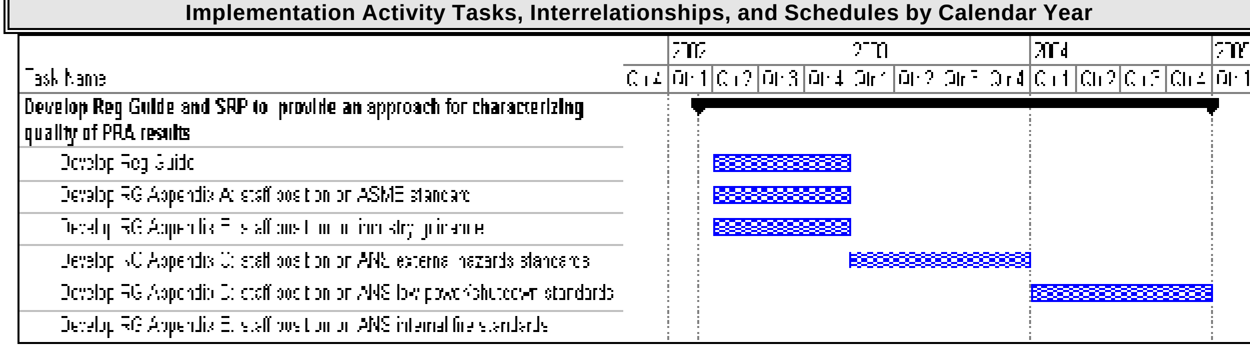
RES Priority: TBD

NRR Priority: TBD

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2002	0.4 (NRR) 0.5 (RES)	250 (RES)
2003	0.1 (NRR) 0.3 (RES)	100 (RES)

Selected Major Milestones and Schedules			
Major Milestones[1]	**Original Target Date**	**Revised Date**	**Completion Date**
Main Body of Reg Guide	12/2002		
Appendix A: Staff position on the PRA standard issued by ASME on internal events	12/2002		
Appendix B: Staff position on the PRA review guidance issued by NEI on internal events (NEI-00-02)	12/0002		
Appendix C: Staff position on PRA standards issued by ANS on External Hazards	12/2003		
Appendix D: Staff position on standards issued by ANS on Low Power/Shutdown	12/2004		
Appendix E: Staff position on PRA standards issued by ANS on internal fire	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



[1]Recognizing that control of these projects rests with the standards committees, milestones have been established by and are under the control of these organizations.