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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-1285

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

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

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes an approach that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for applications for licensing basis changes by considering engineering issues and applying risk insights. It provides general guidance concerning analysis of the risk associated with the proposed changes in plant design and operation.

Applicability

This RG applies to light-water reactor (LWR) licensees subject to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 1), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," (Ref. 2).

Applicable Regulations

- 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit" (Ref. 3), requires that, whenever a holder of a license, including a construction permit and operating license under this part, and an early site permit, combined license, and manufacturing license under 10 CFR Part 52, desires to amend the license or permit, an application for a license amendment must be filed with the Commission fully describing the changes desired.

- 10 CFR 50.92, "Issuance of amendment" (Ref. 4), provides the general considerations which governs the issuance of initial licenses, construction permits, or early site permits to the extent applicable and appropriate.

This regulatory guide is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, http://www.regulations.gov, by searching for DG-1285. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/. The draft regulatory guide is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML16358A153. The regulatory analysis may be found in ADAMS under Accession No. ML16358A156. Responses to public comments received for the 2012 publication of Revision 3 to RG 1.174 may be found in ADAMS under Accession No. ML16348A180.

Related Guidance

- NRC, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (Ref. 5), provides guidance to the NRC staff in performing safety reviews of construction permit or operating license applications (including requests for amendments) under 10 CFR Part 50 and early site permit, design certification, combined license, standard design approval, or manufacturing license applications under 10 CFR Part 52 (including requests for amendments). Section 19.2 of NUREG-0800, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," is designed to guide the NRC staff evaluations of licensee requests for changes to the licensing basis that apply risk insights, as well as guidance developed in selected application-specific RGs and the corresponding chapters of NUREG-0800.

- NRC, RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" (Ref. 6), provides an approach for determining whether the base probabilistic risk assessment (PRA), in total or the parts that are used to support an application, is acceptable such that the base PRA can be used in regulatory decision-making for light-water reactors. RG 1.200 endorses a standard developed by the American Society of Mechanical Engineers and the American Nuclear Society (ASME/ANS), which addresses PRA for core damage frequency (CDF) and large early release frequency (LERF) for internal and external hazard groups at-power.

Purpose of Regulatory Guides

The NRC issues RGs to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG contains voluntary information collections covered by 10 CFR Parts 50 and 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0011 and 3150–0151. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011 and 3150–0151) Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

B. DISCUSSION

Reason for Revision

This revision (Revision 3) presents up-to-date defense-in-depth guidance using precise language to assure the defense-in-depth philosophy is interpreted and implemented consistently. Revision 3 contains significant changes including expansion of the guidance on the meaning of, and the process for, assessing the defense-in-depth evaluation factors.

In addition, this revision adopts the term "PRA Acceptability," including related phrasing variants, in place of the terms "PRA quality" and "technical adequacy" to describe the appropriateness of the PRA used to support risk-informed licensing submittals. Other changes in this revision include expanding the discussions on uncertainties, including aggregation of risk results, consistent with NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking" (Ref. 7), updating the risk acceptance guideline figures, and incorporating discussions related to application of this guide to new reactors.

Background

The Commission directed the staff in the Staff Requirements Memorandum (SRM) on SECY-11-0014, "Staff Requirements – SECY-11-0014 – Use of Containment Accident Pressure in Analyzing Emergency Core Cooling System and Containment Heat Removal System Pump Performance in Postulated Accidents" (Ref. 8), and the SRM on SECY-15-0168, "Staff Requirements – SECY-15-0168 – Recommendations on Issues Related to Implementation of a Risk Management Regulatory Framework" (Ref. 9), to revise the defense-in-depth guidance using precise language to assure the defense-in-depth philosophy is interpreted and implemented consistently.

Both the NRC and the nuclear industry recognize that PRA has evolved to the point that it can be used increasingly as a tool in regulatory decisionmaking. In August 1995, the NRC issued a final Commission policy statement on the use of PRA methods in nuclear regulatory activities titled, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement" (Ref. 10), which adopted the following policy:

- 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, RGs, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109, "Backfitting" (Ref. 11). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed (it should be noted that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised).

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

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

In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: (1) foremost, through safety decisionmaking enhanced by the use of PRA insights, (2) through more efficient use of agency resources, and (3) through a reduction in unnecessary burdens on licensees.

In parallel with the publication of the policy statement, the staff developed an implementation plan to define and organize the PRA-related activities being undertaken. This implementation plan is known as the Risk-Informed and Performance-Based Plan, which is abbreviated as RPP. 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 rely on model changes or simplifying assumptions to change the PRA models so that they reflect the conditions experienced during an operational event. In contrast, other applications require the use of detailed performance and design information to provide a more realistic model of the plant.

The activities described on the agency's public Internet site[1] 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 CDFs for possible backfit. The principal focus of this RG is on the use of PRA findings and risk insights in decisions on proposed changes to a plant's licensing basis.

One significant activity undertaken in response to the policy statement is the use of PRA to support decisions to modify an individual plant's licensing basis. Such modifications are related to changes to a plant's design, operation, or other activities that require NRC approval and could include, for example, exemption requests under 10 CFR 50.12, "Specific exemptions" (Ref. 12) and license amendments under 10 CFR 50.90. This RG does not address licensee initiated changes to the licensing basis that do NOT require NRC review and approval (e.g., changes to the facility as described in the final safety analysis report (FSAR), the subject of 10 CFR 50.59, "Changes, tests and experiments" (Ref. 13)).

This RG also makes use of the Commission's Safety Goal Policy Statement (Ref. 14). As discussed in Section C, one key principle in risk-informed regulation is that proposed increases in risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. The safety goals and associated quantitative health objectives (QHOs) define an acceptable level of risk that is a small fraction (0.1 percent) of other risks to which the public is exposed. The risk acceptance guidelines provided in Section C.2.4 of this RG are defined for LWRs in terms of CDF, LERF, and the change in CDF and LERF (i.e., ΔCDF and ΔLERF) risk metrics. These risk metrics are based on subsidiary objectives derived from the safety goals and their QHOs. In particular, the CDF risk metric is used as a surrogate for the individual latent cancer fatality risk and the LERF risk metric is used as a surrogate for the individual early fatality risk.

As discussed in Section A of this RG, RG 1.200 is an important related guidance document that describes one acceptable approach for determining whether the base PRA, in total or the parts that are used to support an application, is acceptable such that the base PRA can be used in regulatory

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[1] The NRC's Risk-Informed Activities webpage can be accessed at https://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html.

decisionmaking for LWRs. Figure 1, which is taken from RG 1.200, is intended to illustrate the relationship of this RG to some risk-informed activities, other application-specific guidance, RG 1.200, consensus PRA standards, and industry programs.

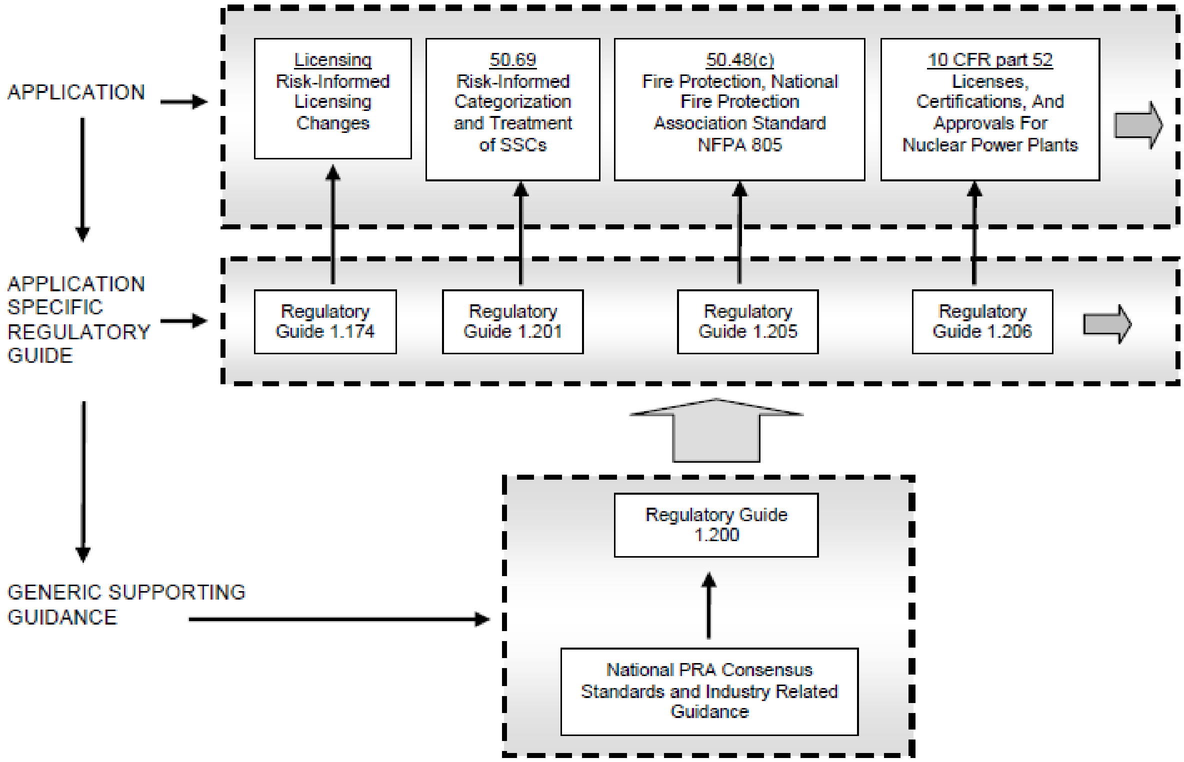

Figure 1. Relationship of Regulatory Guide 1.174 to other risk-informed guidance

This regulatory guide describes an acceptable approach for assessing the nature and impact of proposed licensing basis (LB) changes by considering engineering issues and applying risk insights. These 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. Consideration of the Commission's Safety Goal Policy Statement is an important element in regulatory decisionmaking. Consequently, this guide provides acceptance guidelines for evaluating the results of such assessments that are consistent with this policy statement. This guide also addresses implementation strategies and performance monitoring plans associated with LB changes that will help to ensure that assumptions and analyses supporting the change are verified.

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 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.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guides and standards constituting a high level of safety for protecting people and the environment. IAEA safety guides present international good practices and increasingly reflects best practices to help users striving to achieve high levels of safety. Pertinent to this RG are the following documents:

- IAEA Safety Guide SSG-3, "Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," issued April 2010 (Ref. 15).

- IAEA Safety Guide SSG-4, "Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," issued May 2010 address PRA concepts (Ref. 16).

- IAEA Safety Standards SSR-2/1, "Safety of Nuclear Power Plants: Design," issued January 2012 (Ref. 17).

- IAEA Safety Standard SF-1, "Fundamental Safety Principles," issued November 2006 (Ref. 18).

These safety guides provide recommendations for performing or managing a probabilistic safety assessment project for nuclear power plants and using it to support safe design and operation. This RG discusses some of the same principles with respect to changes to a plant's licensing basis.

NUREG/KM-0009, "Historical Review and Observations of Defense-in-Depth" (Ref. 19), provides a summary of the various descriptions, discussions, and definitions of defense-in-depth that have been used in literature as well as historical observations on the concept of defense-in-depth. It also references international technical documents relevant to this RG including those that provide different perspectives on and interpretations of defense-in-depth philosophy, which were considered as part of the development of related guidance in this RG.

C. STAFF REGULATORY GUIDANCE

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

The staff has defined in this RG an acceptable approach to analyzing and evaluating proposed licensing basis 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.

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 licensing basis to justify that the chosen risk assessment approach, methods, and data are appropriate for the decision to be made.

In implementing risk-informed decisionmaking, licensing basis 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 used, and are encouraged, to help ensure and show that these principles are met. These principles include the following:

- Principle 1: The proposed licensing basis change meets the current regulations unless it is explicitly related to a requested exemption (i.e., a specific exemption under 10 CFR 50.12).

- Principle 2: The proposed licensing basis change is consistent with the defense-in-depth philosophy.

- Principle 3: The proposed licensing basis change maintains sufficient safety margins.

- Principle 4: When proposed licensing basis changes result in an increase in risk, the increases should be small and consistent with the intent of the Commission’s Safety Goal Policy Statement titled, “Safety Goals for the Operations of Nuclear Power Plants; Policy Statement.”

- Principle 5: The impact of the proposed licensing basis change should be monitored using performance measurement strategies.

Each of these principles should be considered in the risk-informed, integrated decisionmaking process, as illustrated in Figure 2.

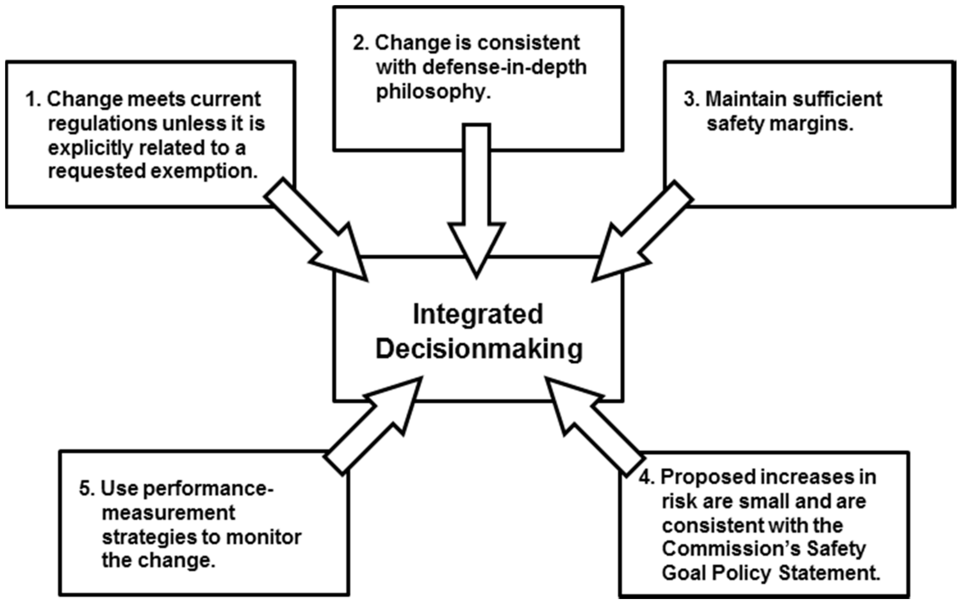

Figure 2. Principles of risk-informed integrated decisionmaking

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

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

- The engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed licensing basis change should (1) be appropriate for the nature and scope of the change, (2) be based on the as-built and as-operated and maintained plant, and (3) reflect operating experience at the plant. The ASME/ANS standard endorsed by RG 1.200 defines as-built, as-operated as a conceptual term that reflects the degree to which the PRA matches the current plant design, plant procedures, and plant performance data, relative to a specific point in time (see Section C.2.3 of this RG for additional information on the relationship between RG 1.174 and the ASME/ANS standard). Acceptability of the engineering analyses is determined by assessing the scope, level of detail, supporting technical analyses, and plant representation.

- The plant-specific PRA supporting the licensee's proposals has been demonstrated to be acceptable.

- Appropriate consideration of uncertainty is given in the analyses and interpretation of findings, including use of a program of monitoring, feedback, and corrective action to address key sources of uncertainty. NUREG-1855 provides acceptable guidance for the treatment of uncertainties in risk-informed decisionmaking.

- The use of CDF and LERF as bases for PRA acceptance guidelines is an acceptable approach to address Principle 4. Use of the Commission's Safety Goal QHOs in lieu of CDF and 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. Guidance on risk metrics for plants licensed under 10 CFR Part 52 is provided later in this section.

- Increases in CDF and LERF resulting from proposed licensing basis changes should be limited to small increments. The cumulative effect of such changes, both risk increase and risk decrease (if available), should be tracked and considered in the decision process. For purposes of this guide, a proposed licensing basis change that meets the acceptance guidelines discussed in Section C.2.2.4 of this RG is considered to have met the intent of the policy statement.

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

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

As related to the use of LERF as a surrogate for the early fatality QHO, LERF is defined as the sum of the frequencies of those accidents leading to rapid, unmitigated release of airborne fission products from the containment to the environment occurring before the effective implementation of offsite emergency response and protective actions such that there is the potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure shortly after vessel breach, containment bypass events, and loss of containment isolation. This definition is consistent with accident analyses used in the safety goal screening criteria discussed in the Commission's regulatory analysis guidelines. NUREG/CR-6595, "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events" (Ref. 20), describes a simple screening approach for calculating LERF.

Given the principles of risk-informed decisionmaking discussed above, the staff has identified a four-element approach to evaluating proposed licensing basis changes. This approach, which Figure 3 presents graphically, supports the NRC's decisionmaking process. This approach is not sequential in nature; rather it is iterative.

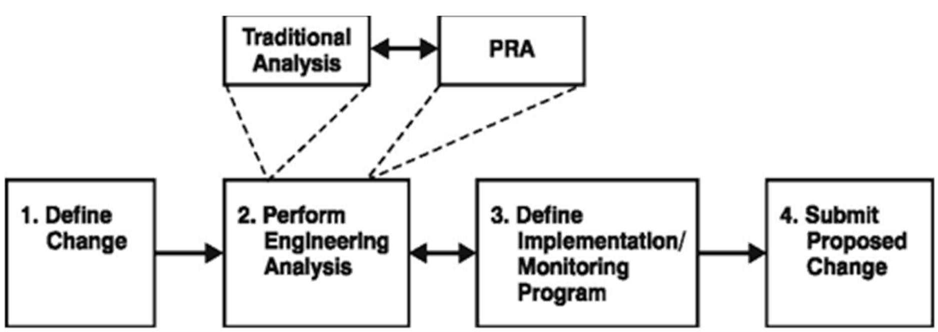

Figure 3. Principal elements of risk-informed, plant-specific decisionmaking

The NRC considers the following approach to be acceptable for use in assessing the nature and impact of proposed licensing basis changes. This approach assesses the impact of the risk associated with the proposed changes in plant design and operation by considering engineering issues and applying risk insights.

Plants should transition at or before their initial fuel load (e.g., following the 10 CFR 52.103(g) finding) from the use of the CDF, large release frequency, and conditional containment failure probability risk metrics and acceptance guidelines used in the design certification and combined license applications to the CDF and LERF risk metrics and acceptance guidelines for risk-informed applications used in this RG. More information can be found in the SRM on SECY-12-0081, "Staff Requirements – Secy-12-0081 – Risk-Informed Regulatory Framework for New Reactors" (Ref. 21).

In addition, for plants licensed under 10 CFR Part 52, the deterministic containment performance metric should also be maintained. The designs certified by the NRC under 10 CFR Part 52 implement design features that are in addition to those required by 10 CFR Part 50, particularly features for severe accidents. The requirements for these design features were codified in the Appendixes to 10 CFR Part 52 for each certified design in a section titled "Applicable Regulations." The certified designs include features to ensure containment performance. Plants licensed under 10 CFR Part 52 should ensure that the containment maintains its role as a reliable, leak-tight barrier for approximately 24 hours following the onset of core damage under the more likely severe accident challenges and, following this 24-hour period, the containment should continue to provide a barrier against the uncontrolled release of fission products. More information can be found in SECY-90-016, "Evolutionary Light-Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements" (Ref. 22), and SECY-93-087, "Policy, Technical, and Licensing issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs" (Ref. 23), as approved by the SRM on SECY-90-016, "Evolutionary Light-Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements" (Ref. 24) and the SRM on SECY-93-087, "Policy, Technical, and Licensing issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs" (Ref. 25), respectively.

1. Element 1: Define the Proposed Change

Element 1 involves three primary activities. First, the licensee should identify those aspects of the plant's licensing basis that may be affected by the proposed change, including but not limited to rules and regulations, FSAR, technical specifications, licensing conditions, and licensing commitments.

Second, the licensee should identify all structures, systems, and components (SSCs), procedures, and activities that are covered by the licensing basis change being evaluated and should consider the original reasons for including each program requirement. When considering licensing basis changes, a licensee may identify regulatory requirements or commitments in its licensing basis 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 licensing basis 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 licensing basis 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 licensing basis change.

The above information should be used collectively to describe the licensing basis change and to outline the method of analysis. The licensee should describe the proposed change and how it meets the objectives of the Commission's PRA Policy Statement, 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 licensing basis change such as reduced fiscal and personnel resources and radiation exposure. The licensee should affirm that the proposed licensing basis change meets the current regulations unless the proposed change is explicitly related to an exemption (i.e., a specific exemption under 10 CFR 50.12).

1.1 Combined Change Requests

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

- CCRs in which any individual change increases risk; or
- CCRs in which each individual change decreases risk.

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

1.2 Guidelines for Developing Combined Change Requests

The changes that make up a CCR should be related to one another (e.g., they affect the same single system or activity, they affect the same safety function or accident sequence or group of sequences, or they are the same type, such as changes in outage time allowed by technical specifications). However, this does not preclude acceptance of unrelated changes. When CCRs are submitted to the NRC staff for review, the relationships among the individual changes and how they have been modeled in the risk assessment should be addressed in detail, since this controls the characterization of the net result of the changes. Licensees should evaluate the individual changes, and also the changes taken in aggregate, against the safety principles and qualitative acceptance guidelines in Part C of this RG. 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 C.2.4 of this guide should be assessed.

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

Proposed changes that modify one or more individual components of a previously approved CCR should also address the impact on the previously approved CCR. Specifically, the licensee should address whether the proposed modification would cause the previously approved CCR to become unacceptable. If this is the case, the submittal should address the actions the licensee is taking with respect to the previously approved CCR.

2. Element 2: Perform Engineering Analysis

The engineering analyses conducted to justify any proposed licensing basis change should be appropriate for the nature and scope of the proposed change. The licensee should appropriately consider uncertainty in the analysis and interpretation of findings. The licensee should use judgment on the complexity and difficulty of implementing the proposed licensing basis change in deciding upon appropriate engineering analyses to support regulatory decisionmaking. Thus, the licensee should consider the appropriateness of qualitative and quantitative analyses, as well as analyses using traditional engineering approaches and those techniques associated with the use of PRA findings. Regardless of the analysis methods chosen, the licensee should show that it has met the principles set forth in Part C of this RG through the use of scrutable acceptance guidelines established for making that determination.

Some proposed licensing basis changes can be characterized as involving the categorization of SSCs according to safety significance. An example is grading the application of special treatment requirements commensurate with the safety significance of equipment under 10 CFR 50.69, “Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Plants” (Ref. 26). Related to other applications, the staff’s review of licensing basis change requests for applications involving safety categorization should be in accordance with the acceptance guidelines associated with each key principle presented in this RG, unless the licensee proposes alternative, equivalent guidelines. Since risk-importance measures are often used in such categorizations, Appendix A to this RG provides guidance on their use. Other application-specific guidance documents address guidelines associated with the adequacy of programs (in this example, special treatment requirements) implemented for different safety-significant categories (e.g., more safety significant and less safety significant). Licensees are encouraged to apply risk-informed findings and insights to decisions (and potential licensing basis requests).

As part of Element 2, the licensee should evaluate the proposed licensing basis change with regard to the principles of maintaining consistency with the defense-in-depth philosophy, maintaining sufficient safety margins, and ensuring that proposed increases in CFR and LERF are small and are consistent with the intent of the Commission’s Safety Goal Policy Statement.

2.1 Evaluation of Defense-in-Depth and Safety Margins

One aspect of the engineering evaluation is to show that the proposed licensing basis change does not compromise the fundamental safety principles on which the plant design and operation (i.e., activities such as maintenance, testing, inspection, and qualification) was based. During the design process, plant response and associated safety margins are evaluated using assumptions of physical properties and operating characteristics that are intended to be conservative. Consideration of national standards, the defense-in-depth philosophy, and the single-failure criterion constitute additional engineering considerations that also influence plant design and operation.

A licensee’s proposed licensing basis change might affect safety margins and defenses incorporated into the current plant design and operation; therefore, the licensee should reevaluate the safety margins and layers of defense to support the proposed change. As part of this evaluation, the impact of the proposed licensing basis change on the functional capability, reliability, and availability of affected equipment should be determined. The plant’s licensing basis is the reference point for judging whether a proposed licensing basis change adversely affects safety margins or defense-in-depth. Sections C.2.1.1 and C.2.1.2 below provide guidance on assessing whether implementation of the proposed licensing basis change maintains adequate safety margins and consistency with the defense-in-depth philosophy.

2.1.1 Defense-in-Depth

The engineering evaluation should demonstrate whether the implementation of the proposed licensing basis change is consistent with the defense-in-depth philosophy. In this regard, the intent of this key principle of risk-informed decisionmaking is to ensure that any impact of the proposed licensing basis change on defense-in-depth is fully understood and addressed and that consistency with the defense-in-depth philosophy is maintained. The intent is not to prevent changes in the way defense-in-depth is achieved. The licensee should fully understand how the proposed licensing basis change impacts plant design and operation from both risk and traditional engineering perspectives.

Section C.2.1.1.1 provides a brief background on the defense-in-depth philosophy. Section C.2.1.1.2 provides a discussion of seven factors that should be used to evaluate the impact of the proposed licensing basis change on defense-in-depth. Section C.2.1.1.3 provides guidance on a process for evaluating the seven defense-in-depth evaluation factors, and Section C.2.1.1.4 provides guidance on the integrated evaluation that should be conducted to demonstrate the application of this guidance.

2.1.1.1 Background

Defense-in-depth is an element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy has traditionally been applied in plant 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 and, in particular, to account for the potential for unknown and unforeseen failure mechanisms or phenomena that, because they are unknown or unforeseen, are not reflected in either the PRA or traditional engineering analyses. The SRM on SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation" (Ref. 27), provides additional information on defense-in-depth as an element of the NRC's safety philosophy.

In addition, some flexibility can be gained in the operations and maintenance of the nuclear plant that leverages the implementation of the defense-in-depth philosophy in the design of the plant. For example, testing and maintenance of SSCs or corrective action to restore an engineered safety system might be allowed for short periods while remaining at power consistent with established technical specifications. The NRC recognizes and allows these temporary configurations within these established programs. If a licensee proposes a licensing basis change that permits new or extended entry into a temporary condition, the licensee should demonstrate that the new or extended entry into that temporary condition is justified and that consistency with the defense-in-depth philosophy is maintained as described in this section.

Defense-in-depth is often characterized by varying layers of defense, each of which may be representative of conceptual attributes of nuclear power plant design and operation or tangible objects such as the physical barriers between fission products and the environment. The NRC implements defense-in-depth as four layers of defense that are a mixture of conceptual constructs and physical barriers (See NUREG/KM-0009 for further detail). As such, for the purposes of this RG, nuclear power plant defense-in-depth is taken to consist of layers of defense (i.e., successive measures) to protect the public:

- Robust plant design to survive hazards and minimize challenges that could result in an event occurring.

- Prevention of a severe accident (core damage) should an event occur.

- Containment of the source term should a severe accident occur.

- Protection of the public from any releases of radioactive material (e.g., through siting in low population areas and the ability to shelter or evacuate people, if necessary).

2.1.1.2 Factors for Evaluating the Impact of the Proposed Licensing Basis Change on Defense-in-Depth

Any one or more of the layers of defense discussed above might be adversely impacted by the proposed licensing basis change. The NRC has identified seven factors that should be used to evaluate the impact of the change on defense-in-depth. These are discussed in detail below. Section C.2.1.1.3 discusses guidance on how to apply these factors in more detail.

The NRC finds it acceptable for a licensee to use the following seven factors to evaluate how the proposed licensing basis change impacts defense-in-depth.

1. Preserve a reasonable balance among the layers of defense.

   A reasonable balance of the layers of defense-minimizing challenges to the plant, preventing any events from progressing to core damage, containing the radioactive source term, and emergency preparedness, helps to ensure an apportionment of the plant's capabilities between limiting disturbances to the plant and mitigating their consequences. The term reasonable balance is not meant to imply an equal apportionment of capabilities. The NRC recognizes that aspects of a plant's design or operation might cause one or more of the layers of defense to be adversely affected. For these situations, the balance between the other layers of defense becomes especially important when evaluating the impact of the proposed licensing basis change and its impact on defense-in-depth.

2. Preserve adequate capability of design features without an overreliance on programmatic activities as compensatory measures.

   Nuclear power plant licensees implement a number of programmatic activities including, for example, programs for quality assurance, testing and inspection, maintenance, control of transient combustible material, foreign material exclusion, containment cleanliness, training, and so forth. In some cases, activities taken as part of these programs are used as compensatory measures, that is measures taken to compensate for some reduced functionality, availability, reliability, redundancy, or other feature of the plant's design to ensure safety functions (e.g., reactor vessel inspections that provide assurance that reactor vessel failure is unlikely). Safety function is defined in NUREG-2122, "Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking" (Ref. 28), as those functions needed to shut down the reactor, remove the residual heat, and contain any radioactive material release.

   A proposed licensing basis change might involve or require compensatory measures, which could include, for example, hardware (e.g., skid-mounted temporary power supplies); human actions (e.g., manual system actuation); or some combination of these measures. Such compensatory measures are often associated with temporary plant configurations. The preferred approach for accomplishing safety functions is through engineered systems. Therefore, when the proposed licensing basis change necessitates reliance on programmatic activities as compensatory measures, the licensee should justify that this reliance is not excessive (i.e., not over reliant). The intent of this factor is not to preclude the use of such programs as compensatory measures but to ensure that the use of such measures does not significantly reduce the capability of the design features (e.g., hardware).

3. Preserve system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to the system, including consideration of uncertainty.

   As stated in Section C.2.1.1 above, the defense-in-depth philosophy has traditionally been applied in plant design and operation to provide multiple means to accomplish safety functions. System redundancy, independence, and diversity result in high availability and reliability of SSCs and also help ensure that system safety functions are not reliant on any single feature of the design. Redundancy provides for duplicate equipment that enables the failure or unavailability of at least one set of equipment to be tolerated without loss of function. Independence among equipment implies that the redundant equipment is separate such that it does not rely on the same supports to function. It can sometimes be achieved by the use of physical separation or physical protection. Diversity is accomplished by having equipment that performs the same function rely on different attributes such as different principles of operation, different physical variables, different conditions of operation, or production by different manufacturers which helps reduce common cause failure (CCF).

   A proposed change might reduce the redundancy, independence, or diversity of systems. The intent of this factor is to ensure that the ability to provide the system function is commensurate with the risk of scenarios that could be mitigated by that function. The consideration of uncertainty, including the uncertainty inherent in the PRA, implies that the use of redundancy, independence, or diversity provides high reliability and availability and also results in the ability to tolerate failures or unanticipated events.

4. Preserve adequate defense against potential common-cause failures.

   An important aspect of ensuring defense-in-depth is to guard against CCF. Failure of multiple components to function may occur as a result of a single specific cause or event that could simultaneously affect several components important to risk. The cause or event may include an installation or construction deficiency, accidental human action, extreme external environment, or an unintended cascading effect from any other operation or failure within the plant. CCFs can also result from poor design, manufacturing, or maintenance practices.

   To defend against CCF, one should first identify potential coupling factors between equipment failures. A coupling factor is the condition or mechanism through which multiple components could be affected (or coupled) by the same cause. Coupling factors can be based on, but may not necessarily be limited to the following attributes:

   - Inadequate design for the environment or other aspect of the application.

   - Manufacturing error that diminishes the capability of all components of a particular batch or run.

- Detrimental maintenance practices (e.g., incorrect lubricant type or amount, poor performance of maintenance, etc.).

- Support system dependencies (e.g., common power supplies, ventilation, cooling water, etc.).

- Inadequate separation or protection from common hazards such as fires or flooding barriers.

- Common staff, common procedures, or common maintenance, testing, or calibration schedules.

Once coupling factors have been identified, measures may be put in place to minimize the impact of CCF. A variety of defense strategies can be used to decrease the likelihood of component or system unavailability and to minimize the occurrence of CCFs. Preventing and decoupling failures are both important as defenses against CCFs. A defense can prevent the occurrence of failures from the causes and events that could allow simultaneous multiple component failures. An example of this type of defense might be fire or flood barriers that limit component failures from fires of floods to only one train of redundant equipment. Another approach to defend against CCFs is to decouple failures as opposed to preventing the cause of failures. This defense effectively decreases the similarity of components and their environment in some way that prevents a particular type of failure cause from affecting all components simultaneously and allows more opportunity for detecting failures before they appear in all components of the group. An example of this type of defense against CCF is using diverse components to provide the same safety function.

5. Maintain multiple fission product barriers.

   Fission product barriers include the physical barriers themselves (e.g., the fuel cladding, reactor coolant system pressure boundary, and containment) and any equipment relied upon to protect the barriers (e.g., containment spray). In general, these barriers are designed to perform independently so that a complete failure of one barrier does not disable the next subsequent barrier. For example, one barrier, the containment, is designed to withstand a double-ended guillotine break of the largest pipe in the reactor coolant system, another barrier.

   A plant's licensing basis might contain events that, by their very nature, challenge multiple barriers simultaneously. Examples include interfacing-system loss-of-coolant accidents (LOCAs), steam generator tube rupture, or crediting containment accident pressure. Therefore, complete independence of barriers, while a goal, might not be achievable for all possible scenarios.

6. Preserve sufficient defense against human errors.

   Human errors include the failure of operators to perform the actions necessary to operate the plant or respond to off-normal conditions and accidents, errors committed during test and maintenance, and other plant staff performing an incorrect action. Human errors can result in the degradation or failure of a system to perform its function, thereby significantly reducing the effectiveness of one of the layers of defense or one of the fission product barriers. The plant design and operation includes defenses to prevent the occurrence of such errors and events. These defenses generally involve the use of procedures, training, and human engineering; however, other considerations (e.g., communication protocols) might also be important.

7. Continue to meet the intent of the plant's design criteria

   For plants licensed under 10 CFR Part 50 or Part 52, the plant's design criteria are set forth in the current licensing basis of the plant. The plant's design criteria define minimum requirements that achieve aspects of the defense-in-depth philosophy; as a consequence, even a compromise to the intent of those design criteria can directly result in a significant reduction in the effectiveness of one or more of the layers of defense. When evaluating the effect of the proposed licensing basis change, the licensee should demonstrate that the intent of the plant's design criteria continue to be met.

2.1.1.3 Evaluating the Impact of the Proposed Licensing Basis Change on Defense-in-Depth

It is considered acceptable for a licensee to use the seven defense-in-depth evaluation factors described in Section C.2.1.1.2 to evaluate the impact of a proposed licensing basis change on defense-in-depth. It is presumed that, prior to the implementation of the proposed licensing basis change, the as-built and as-operated plant is consistent with the defense-in-depth philosophy. However, there might be situations where a plant is not in compliance with its design basis or licensing basis or new information might arise indicating that the design basis or licensing basis is deficient. In such cases, the as-built and as-operated plant might not be consistent with the defense-in-depth philosophy prior to the implementation of the proposed licensing basis change. When this occurs, the licensee and the staff should ensure compliance with existing requirements (e.g., regulations, license conditions, orders, etc.) and implement appropriate actions to address any non-compliances. When addressing these deficiencies or non-compliances, consideration should be given to the concepts in this document to help achieve consistency with the defense-in-depth philosophy. Although the guidance is presented separately for each factor, the evaluation of the proposed licensing basis change should be performed in an integrated fashion. The proposed licensing basis change is considered to maintain consistency with the defense-in-depth philosophy if the integrated assessment demonstrates no significant impact on a single factor (i.e., the intent of each defense-in-depth evaluation factor is met). Such an evaluation of the proposed licensing basis change against the seven factors might be qualitative.

The seven defense-in-depth evaluation factors could be arranged in a hierarchical manner. For example, the first factor is an overarching high-level description of how defense-in-depth is achieved. Factors two through six might apply to any of the layers of defense to aid the analyst in justifying that the proposed licensing basis change preserves a reasonable balance among the layers of defense. Finally, factor seven helps ensure completeness of the assessment of how the proposed licensing basis change could impact defense-in-depth. Nevertheless, in the interest of completeness, the seven factors should each be addressed for any proposed licensing basis change. If the proposed licensing basis change has no impact on a given factor, the licensee should state as much including a brief justification. Licensees should structure their discussion of how the proposed licensing basis change impacts defense-in-depth by explicitly addressing the seven factors. Such an approach would facilitate the licensee's analysis as well as make for a more efficient review by the NRC staff.

It is important to note that the focus here is on the effect of the proposed licensing basis change on defense-in-depth. The seven defense-in-depth evaluation factors presented in Section C.2.1.1.2 are not intended to define how defense-in-depth is implemented in a plant's design but are intended to help licensees assess the impact of the proposed licensing basis change on defense-in-depth.

The following discussion provides guidance on how to evaluate the proposed licensing basis change for each of the defense-in-depth evaluation factors:

1. Preserve a reasonable balance among the layers of defense.

   The proposed licensing basis change should not significantly reduce the effectiveness of a layer of defense that exists in the plant design prior to the implementation of the proposed licensing basis change.

   The evaluation of the proposed licensing basis change should consider insights based on traditional engineering approaches; insights from risk assessments might be used to support engineering insights but should not be the only justification for meeting this factor.

   To evaluate this factor, the licensee should address each of the layers of defense in turn. A reasonable balance among the layers of defense is preserved if the proposed licensing basis change does not significantly reduce the effectiveness of a layer of defense that exists in the plant design and operation prior to the implementation of the proposed licensing basis change (i.e., the effectiveness has not been reduced to the extent that the layer no longer provides an acceptable level of defense).

   A comprehensive risk analysis can provide insights into whether the balance among the layers of defense remains appropriate to ensure protection of public health and safety. Such a risk analysis would include the likelihood of challenges to the plant (i.e., initiating event frequencies) from various hazards as well as CDF, containment response, and dose to the public. In addition, qualitative and quantitative insights from the PRA might help justify that the balance across all the layers of defense is preserved.

   Note that the risk acceptance guidelines in this RG are based on the surrogates for the Commission's quantitative health objectives CDF and LERF. These risk metrics, developed as part of the risk assessment, can help inform the licensee's assessment of the relative balance between the prevention of core damage and containment of the radioactive source term.

   However, to address the unknown and unforeseen failure mechanisms or phenomena, the licensee's evaluation of this defense-in-depth evaluation factor should also address insights based on traditional engineering approaches. Results and insights of the risk assessment might be used to support the conclusion; however, the results and insights of the risk assessment should not be the only basis for justifying that this defense-in-depth evaluation factor is met. The licensee should consider the impact of the proposed licensing basis change on each of the layers of defense:

   - Robust plant design to survive hazards and minimize challenges that could result should an event occur – The change should not significantly increase the likelihood of initiating events or create new significant initiating events.

   - Prevention of a severe accident (core damage) should an event occur – The change should not significantly impact the availability and reliability of SSCs that provide the safety functions that prevent plant challenges from progressing to core damage.

- Containment of the source term should a severe accident occur – The change should not significantly impact the containment function or SSCs that support that function such as containment fan coolers and sprays.

- Protection of the public from any releases of radioactive material – The change should not significantly reduce the effectiveness of the emergency preparedness program including the ability to detect and measure releases of radioactivity, notify offsite agencies and the public, and shelter or evacuate the public as necessary.

2. Preserve adequate capability of design features without an overreliance on programmatic activities as compensatory measures.

   The proposed licensing basis change should not substitute programmatic activities for design features to an extent that significantly reduces the reliability and availability of design features to perform their safety functions without overreliance on programmatic activities.

   The evaluation of the proposed licensing basis change should demonstrate that the change does not result in an excessive reliance on programmatic activities that are used to compensate for an intended reduction in the capability of engineered safety features.

   To evaluate this factor, the licensee should first determine whether the proposed licensing basis change necessitates compensatory measures. If not, this should be stated as the reason this factor is met. If compensatory measures are needed to support the proposed licensing basis change, the licensee should determine the extent to which programmatic activities, as compared to design features, are being relied upon. The intent of this factor is not to preclude the use of programs as compensatory measures but to ensure that reliance on programmatic activities as compensatory measures for a reduction in the capability of a design feature is not excessive.

   A proposed licensing basis change that does not affect how safety functions are performed or reduce the reliability or availability of the SSCs that perform those functions would meet this defense-in-depth factor. However, a licensee could contemplate a change where a reduction in the capability of those SSCs is compensated in some manner by reliance on plant programs (i.e., programmatic activities). In such a case, the licensee should assess whether the proposed licensing basis change would increase the need for programmatic activities to compensate for the lack of engineered features. If the proposed licensing basis change requires reliance on new programmatic activities or additional reliance on existing programmatic activities as a substitute for reliance on a design feature, the licensee should justify that the proposed reliance on the programmatic activities in place of design features is not excessive. Reliance on a programmatic activity as a compensatory measure might be considered excessive when a program is substituted for an engineered means of performing a safety function or when the failure of the programmatic activity could prevent an engineered safety feature from performing its intended function.

   The NRC also recognizes that compensatory measures are sometimes associated with temporary conditions. A licensee might propose a risk-informed licensing basis change to permit occasional entry into conditions requiring measures that rely on plant programs to compensate for reduced capability of engineered systems or for one-time to allow completion of corrective action to restore engineered systems to match the design and licensing basis. For such situations, the licensee should demonstrate that the plant condition requiring such compensatory measures would occur at a sufficiently low frequency or that the timeframe to implement corrective action is commensurate with the significance of the nonconforming condition.

3. Preserve system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to the system including consideration of uncertainty.

   The proposed licensing basis change should not significantly reduce the redundancy, independence, or diversity of systems.

   The evaluation of the proposed licensing basis change should demonstrate that the change does not result in a significant increase in the expected frequency of challenges to the system or consequences of failure of the system functions as a result of a decrease in redundancy, independence, or diversity.

   To evaluate this factor, the licensee should demonstrate that any reduction in redundancy, independence, or diversity of systems does not result in a significant increase in risk. This evaluation should determine whether the proposed licensing basis change: (1) is consistent with the assumptions in the plant's safety analysis, if applicable; (2) increases the frequency of challenges to the plant resulting from failure of the system; and (3) decreases the reliability or availability of the system to perform its intended functions. For items 2 and 3, the licensee should consider whether any increase in frequency or decrease in dependability results in a significant increase in risk from one type of hazard or scenario. If the risk impact of the proposed licensing basis change is significant, then it is not commensurate with the importance of the system. The ability to accomplish a safety function might be substantially reduced if one of the plant features that provides system redundancy, independence, or diversity is defeated. This adverse impact could occur by the introduction of a new dependency that could potentially defeat the redundancy, independence, or diversity of the affected equipment. Plant changes that introduce new dependencies among systems or functions or that introduce new CCFs (addressed under Factor 4) should not result in a disproportionate increase in risk.

   Some proposed licensing basis changes allow the plant to be in an operational condition where certain design features are not available to perform their intended functions for some specified period of time. For example, a single train of a multi-train system might be out of service. It is not the intent of this factor of defense-in-depth to preclude such temporary plant configurations. Other controls on temporary plant configurations, such as the Technical Specifications, limit the exposure to risk during such periods.

4. Preserve adequate defense against potential common-cause failures.

   The proposed licensing basis change should not significantly reduce defenses against CCFs that could defeat the redundancy, independence, and/or diversity of the layers of defense, fission product barriers, and the design, operational, or maintenance aspects of the plant.

   The evaluation of the proposed licensing basis change should demonstrate that the change does not result in a significant reduction of existing CCF defenses or introduce new CCF dependencies.

Two general approaches exist for defending against CCF: (1) defend against the failure cause or event and (2) defend against the CCF coupling factor. A combination of both approaches may be employed. The licensee should determine that the proposed licensing basis change does not reduce existing defense strategies or introduce a new cause, event, or coupling factor.

To evaluate this factor, the licensee should determine whether the proposed licensing basis change could:

- Introduce a new potential CCF cause or event for which a defense is not in place.

- Increase the probability or frequency of a cause or event that could cause simultaneous multiple component failures.

- Introduce a new coupling factor for which a defense is not in place.

- Weaken or defeat an existing defense against a cause, event, or coupling factor.

It is recognized that the PRA model explicitly models some types of CCF so that the risk assessment provides some insights into this factor for evaluating defense-in-depth. However, the licensee should also qualitatively evaluate whether the change has adversely impacted any of the three areas above to judge whether this factor has been met.

5. Maintain multiple fission product barriers.

The proposed licensing basis change should not significantly reduce the effectiveness of the multiple fission product barriers.

The evaluation of the proposed licensing basis change should demonstrate that the change does not:

- Create a significant increase in the likelihood or consequence of an event that simultaneously challenges multiple barriers.

- Introduce a new event that would simultaneously impact multiple barriers.

To evaluate this factor, the licensee should consider achieving the following objectives to ensure that the proposed licensing basis change maintains consistency with the defense-in-depth philosophy:

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

- The proposal does not significantly increase 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.

6. Preserve sufficient defense against human errors.

The proposed licensing basis change should not significantly increase the potential for or create new human errors that might adversely impact one or more layers of defense.

The evaluation of the proposed licensing basis change should demonstrate that the change does not adversely affect the ability of plant staff to perform actions.

To evaluate this factor, the licensee should determine whether the proposed licensing basis change would:

- Create new human actions that are important to preserving any of the layers of defense.

- Place a significantly increased mental or physical demand on individuals responding to events.

- Significantly increase the probability of existing human errors.

Consideration of human actions should include errors for operators, maintenance personnel, and other plant staff.

7. Continue to meet the intent of the plant's design criteria.

The proposed licensing basis change should not affect meeting the intent of the plant's design criteria referenced in the licensing basis.

The evaluation of the proposed licensing basis change should demonstrate that the change does not significantly compromise meeting the intent of the plant's design criteria thereby significantly reducing the effectiveness of one or more layers of defense.

To evaluate this factor, the licensee should consider the current licensing basis of the plant and determine how the proposed licensing basis change would meet the intent of the plant's design criteria and, for plants licensed under 10 CFR Part 52, meet the intent of the severe accident design features. In doing so, the licensee should demonstrate a full understanding of any impacts that the proposed licensing basis change might have on the design criteria or severe accident design features of the plant. It is recognized that, in general, the consideration of applicable regulations under the first principle of risk-informed regulation might fully address this defense-in-depth evaluation factor. Also, it is not the intent of this factor that changes to the plant's design criteria or severe accident design features cannot be requested.

For some hazards and for some licensees, defense-in-depth might be defined in the plant's licensing basis. For example, the fire protection program for licensed nuclear power plants requires that fire protection defense-in-depth, which is scenario-based, be maintained. Any proposed licensing basis change should be evaluated against any plant-specific licensing basis defense-in-depth requirements in addition to the guidance presented herein.

In addition, for plants licensed under 10 CFR Part 52, this factor should also address those design features for the prevention and mitigation of severe accidents that are described and analyzed in accordance with 10 CFR 52.47(a)(23) and 10 CFR 52.79(a)(38). Section

C.I.19.8 of RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)" (Ref. 29), provides guidance on implementing these requirements and ties the requirements to the issues and performance goals identified in SECY-90-016 and SECY-93-087, which the Commission approved in their respective SRMs on SECY-90-016 and SECY-93-087.

Also, RG 1.216, "Containment Structural Integrity Evaluation for Internal Pressure Loadings above Design-Basis Pressure" (Ref. 30), provides acceptable methods for an analysis that specifically addresses the issues and performance goals identified in SECY-90-016 and SECY-93-087 and related SRMs on containment structures in nuclear power plants under severe accident conditions. For this factor, the potential impacts on these severe accident design features should also be evaluated to ensure the intent of these design features continue to be met.

2.1.1.4 Integrated Evaluation of the Defense-in-Depth Evaluation Factors

The guidance for evaluation of the seven factors described above should enable the licensee to demonstrate the impact of a proposed licensing basis change on defense-in-depth. The licensee should be able to conclude whether the change maintains consistency of the plant design with the defense-in-depth philosophy by showing that the intent of each factor is still met following the implementation of the proposed licensing basis change.

The evaluation should demonstrate the licensee's understanding of how the change impacts plant design and operation both from risk and traditional engineering perspectives.

2.1.2 Safety Margin

The engineering evaluation should assess whether the impact of the proposed licensing basis 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 licensing basis change were to be implemented. An acceptable set of guidelines for making that assessment is summarized below. Other equivalent acceptance guidelines may also be used. With sufficient safety margins, the following are true:

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

The NRC has developed application-specific guidelines reflecting this general guidance that may be found in the application-specific RGs such as RG 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing" (Ref. 31), RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications" (Ref. 32), RG 1.178, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping" (Ref. 33), and RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance" (Ref. 34).

2.2 Evaluation of Risk Impact, Including Treatment of Uncertainty

The licensee may use its risk assessment to address the principle that proposed increases in CDF and LERF are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. For purposes of implementation, the licensee should assess the expected change in CDF and LERF. For licensing basis changes that may have a substantial impact, an in-depth and comprehensive risk assessment, in the form of a PRA (i.e., a PRA that is appropriate to derive the total impact of the proposed licensing basis change) may be necessary to provide acceptable justification. As discussed in RG 1.200, a method or approach is considered to be a PRA when the method or approach (1) provides a quantitative assessment of the identified risk in terms of scenarios that result in undesired consequences (e.g., core damage or a large early release) and their frequencies, and (2) is comprised of specific technical elements in performing the quantification." Section C.1.2 of RG 1.200 defines the technical elements.

As discussed in Section C.2.4, the risk acceptance guidelines are intended for comparison with the results of a full scope risk assessment. However, the necessary sophistication of the evaluation, including the scope of the PRA (e.g., internal hazards only, at-power only), depends on the contribution the risk assessment makes to the integrated decisionmaking, which depends to some extent on the magnitude of the potential risk impact. It should be noted that because the hazards and plant operating states are independent, addition of the mean value risk results (also referred to as "aggregation" of the results) of the contributions is mathematically correct.

In other applications, calculated risk-importance measures or bounding risk calculations may be adequate. In still others, a qualitative assessment of the impact of the licensing basis 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:

- A fundamental element of NRC's risk-informed regulatory process is a PRA of sufficient scope, level of detail, conformance to technical elements, and plant representation for the intended application. Section C.2.3 of this guide discusses the staff's expectations with respect to the acceptability of the PRA for an application.

- PRA results are to be used in this decisionmaking process in two ways: (1) to assess the overall base CDF/LERF of the plant and (2) to assess the CDF/LERF impact of the proposed change. Section C.2.4 of this guide discusses the acceptance guidelines for each of these measures.

- 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 C.2.5 of this guide provides guidelines on how the uncertainty should be addressed in the decisionmaking process.

The staff bases its decision on the proposed licensing basis change on its independent judgment and review of the entire application.

2.3 Determining the Acceptability of a Probabilistic Risk Assessment

The PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, conformance with the technical elements, and plant representation. These aspects 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 various aspects of the PRA can be reduced if a proposed change to the LB results in a risk decrease or a change that is very small, or if the decision could be based mostly on traditional engineering arguments, or if compensating measures are proposed such that it can be convincingly argued that the change is very small. A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices. RG 1.200 describes one acceptable approach for determining whether the acceptability of the base PRA, in total or the parts that are used to support an application, is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decisionmaking for light-water reactors.

Specifically, RG 1.200 provides guidance for the following:

- an acceptable PRA

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

- demonstration that the baseline PRA (in total or specific parts) used in regulatory applications is acceptable, and

- documentation of the acceptability of the PRA to support a regulatory submittal.

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

RG 1.200 endorses an ASME/ANS standard that addresses the base PRA for CDF and LERF for internal and external hazard groups at-power. Other standards for low power and shutdown modes of operation and Level 2 PRAs, for example, are under development.

This RG is intended for a variety of applications, consequently the scope, level of detail, conformance with the technical elements, and plant representation may vary. 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.

2.3.1 Probabilistic Risk Assessment Scope to Support an Application

The scope of a PRA is defined in terms of the causes of initiating events and the plant operating modes it addresses. The causes of initiating events are classified into hazard groups. A hazard group is defined as a group of similar hazards that are assessed in a PRA using a common approach, methods, and likelihood data for characterizing the effect on the plant. Typical hazard groups considered in a nuclear power plant PRA include internal events, internal floods, seismic events, internal fires, high winds, external flooding, etc. For additional guidance on the scope of the base PRA, see Regulatory Position C.1.1 in RG 1.200.

The assessment of the risk implications in light of the acceptance guidelines discussed in Section C.2.4 of this guide suggests that all plant operating modes and hazard groups be addressed, however, it is not always necessary to have a PRA of such scope. A qualitative treatment of the missing modes and hazard groups may be sufficient when the licensee can demonstrate that those risk contributions would not affect the decision; that is, they do not alter the results of the comparison with the acceptance guidelines in Section C.2.4 of this guide. However, as stated in the SRM on SECY-04-0118, "Plan for the Implementation of the Commission's Phased Approach to Probabilistic Risk Assessment Quality" (Ref. 35), when the risk associated with a particular hazard group or operating mode would affect the decision being made, it is the Commission's policy that, if a staff-endorsed PRA standard exists for that hazard group or operating mode, then the risk should be assessed using a PRA that meets that standard. Section C.2.5 of this guide discusses this further.

2.3.2 Probabilistic Risk Assessment Technical Elements to Support an Application

A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices and commensurate with the scope and level of detail required as discussed in Section 2.3.1 and 2.3.3, respectively, and appropriately represents the plant as discussed in Section 2.3.4. Regulatory Guide 1.200 (Ref. 6) describes one acceptable approach for determining conformance with the technical elements needed in a PRA (in total or the parts that are used to support an application). In general, a PRA that is performed correctly is one where the methods are implemented correctly and the assumptions and approximations are reasonable.

The assessment of the risk implications in light of the acceptance guidelines discussed in Section C.2.4 of this guide generally suggests a risk analysis in the form of a PRA. An acceptable PRA is one where the method or approach (1) provides a quantitative assessment of the identified risk in terms of scenarios that result in undesired consequences (e.g., core damage or a large early release) and their frequencies, and (2) is comprised of specific technical elements in performing the quantification. The technical elements are the basic technical analyses that are needed to develop and quantify a PRA model which are defined in the ASME/ANS PRA standard. The specific technical elements can vary depending on the scope of the PRA model, and therefore, as dictated by the application.

The ASME/ANS standard provides technical supporting requirements for each technical element in terms of three Capability Categories. The intent of the delineation of the Capability Categories within the supporting requirements is generally that the degree of level of detail, the degree of plant specificity, and the degree of realism increase from Capability Category I to Capability Category III. In general, the staff anticipates that current good practice, that is, Capability Category II in the ASME/ANS standard is acceptable for the majority of applications. RG 1.200 defines current good practice as those states-of-practice that are generally accepted throughout the industry and have been shown to be technically acceptable in documented analyses or engineering assessments. However, for some applications, Capability Category I may be sufficient for some requirements, whereas for other applications it may be necessary to achieve Capability Category III for specific requirements. It should be noted that in the next edition of the ASME/ANS PRA standard the supporting requirements will only include Capability Categories I and II, and Capability Category III will no longer be included.

2.3.3 Probabilistic Risk Assessment Level of Detail to Support an Application

The level of detail in the PRA should be sufficient to model the impact of the proposed licensing basis 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 of the proposed licensing basis change on the PRA elements. For applications like component categorization, sensitivity studies on the effects of the proposed licensing basis change may be sufficient. For other applications, it may be acceptable to define the qualitative relationship of the impact of the proposed licensing basis change on the PRA elements or to only identify the impacted elements.

If the impacts of a proposed licensing basis change to the plant cannot be associated with elements of the PRA, the PRA should be modified accordingly or the impact of the change should be evaluated qualitatively as part of the integrated decisionmaking process discussed in Section C.2.6 of this guide. The assessment should properly account for the effects of the changes on the reliability and unavailability of SSCs or on operator actions. For additional guidance on level of detail for the base PRA, see Regulatory Position C.1.3 in RG 1.200.

2.3.4 Probabilistic Risk Assessment Plant Representation to Support an Application

The PRA results used to support an application are derived from a base PRA model that represents the as-built and as-operated plant to the extent needed to support the application. Consequently, the PRA should have been maintained and upgraded, where necessary, to ensure it represents the as-built and as-operated plant. For additional guidance on plant representation for the base PRA, see Regulatory Position C.1.4 in RG 1.200.

2.4 Acceptance Guidelines

The risk-acceptance guidelines presented in this RG are based on the principles and expectations for risk-informed regulation discussed in Part C of this RG and are structured as follows. Regions are established in the two planes generated by a measure of the base risk metric (CDF or LERF) along the x-axis, and the change in those metrics (ΔCDF or ΔLERF) along the y-axis (Figures 4 and 5). Acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full-scope (including internal and external hazards, at- power, low power, and shutdown) assessment of the change in risk metric and, when necessary, as discussed below, the base 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 C.2.5 of this guide.

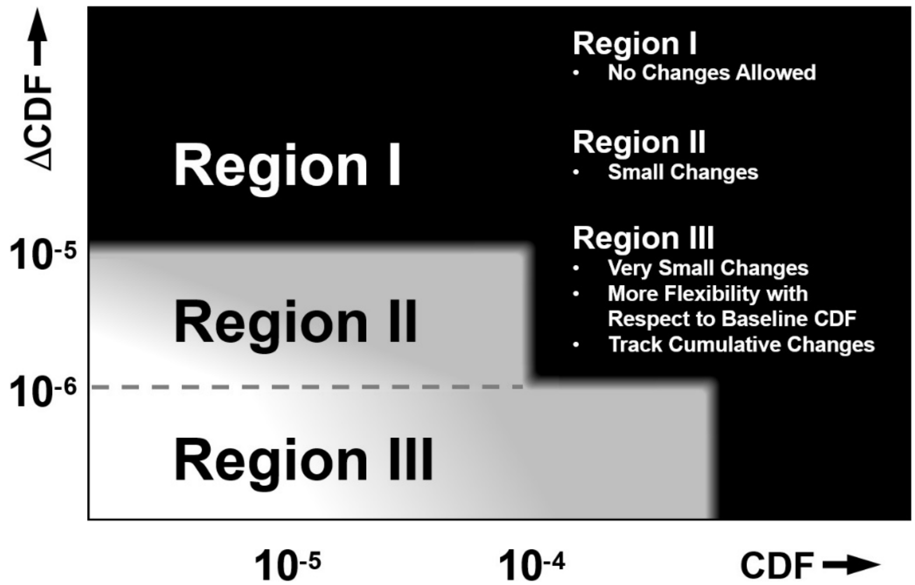

Figure 4. Acceptance guidelines* for core damage frequency

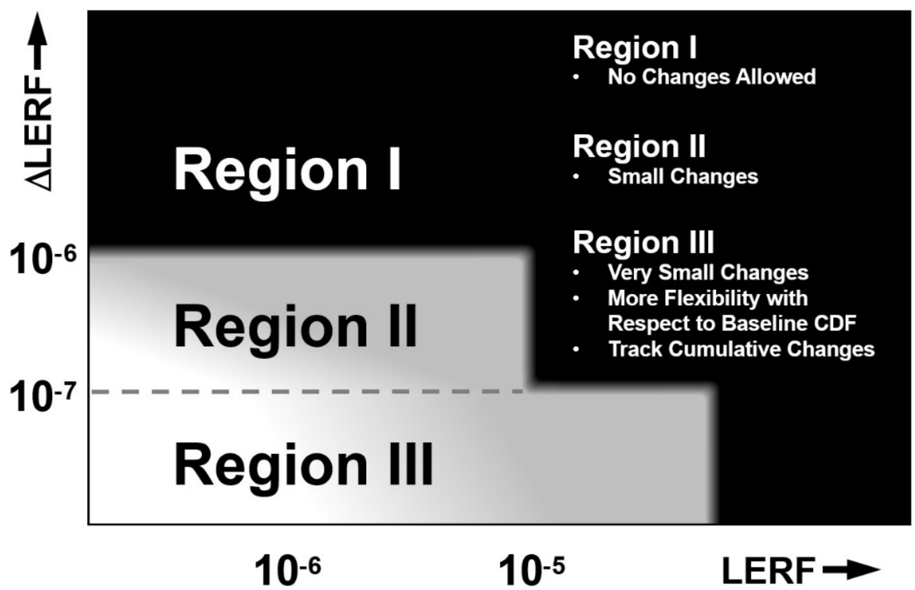

Figure 5. Acceptance guidelines* for large early release frequency

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

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

- If the application clearly shows a decrease in CDF, the change has satisfied the relevant principle of risk-informed regulation with respect to CDF. The region associated with such a change is not represented graphically in Figure 4 given that Figure 4 uses a logarithmic scale.

- When the calculated increase in CDF is very small (i.e., the increase in CDF falls within Region III of Figure 4), which is taken as being less than 10^{-6} per reactor year, the change is considered regardless of whether there is a calculation of the total CDF. 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 (i.e., the increase in CDF falls within Region II of Figure 4), applications are considered only if it can be reasonably shown that the total CDF is less than 10^{-4} per reactor year.

- Applications that result in increases to CDF above 10^{-5} per reactor year (i.e., the increase in CDF falls within Region I of Figure 4) would not normally be considered.

AND

- If the application clearly shows a decrease in LERF, the change has satisfied the relevant principle of risk-informed regulation with respect to LERF. The region associated with such a change is not represented graphically in Figure 5 given that Figure 5 uses a logarithmic scale.

  When the calculated increase in LERF is very small (i.e., the increase in LERF falls within Region III of Figure 5), which is taken as being less than 10^{-7} per reactor year, the change is considered regardless of whether there is a calculation of the total LERF. 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 (i.e., the increase in LERF falls within Region II of Figure 5), applications are considered only if it can be reasonably shown that the total LERF is less than 10^{-5} per reactor year.

- Applications that result in increases to LERF above 10^{-6} per reactor year (i.e., the increase in LERF falls within Region I of Figure 5) 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. As illustrated in footnote to Figures 4 and 5, the boundaries between regions are not definitive. In particular, in applying these guidelines, it is important to recognize that the risk metrics calculated using PRA models are a function of the assumptions and approximations made in the development of those models. This is particularly important when the results from PRA models for multiple hazard groups are combined since the results from some hazard groups, depending on the state of practice, may be conservatively or non-conservatively biased. This is discussed further in Section C.2.5. Section C.6.3.2 provides a discussion on tracking cumulative changes.

As indicated by the shading on the acceptance guideline figures, the change request is subject to an NRC technical and management review that becomes more intensive as the calculated results move closer to the region boundaries.

The guidelines discussed above are applicable for at-power, low-power, and shutdown operations. However, during certain shutdown operations when the containment function is not maintained, the LERF guideline as defined above is not practical. In those cases, licensees may use more stringent base CDF guidelines (e.g., 10^{-5} per reactor year) to maintain an equivalent risk profile or may propose an alternative guideline to LERF that meets the intent of Principle 4 (see Figure 2).

The technical review that relates to the risk evaluation addresses the acceptability of the analysis, including consideration of uncertainties as discussed in the next section. Section C.2.6 of this guide discusses aspects covered by the management review, which include factors that are not amenable to PRA evaluation.

2.5 Comparison of Probabilistic Risk Assessment Results with the Acceptance Guidelines

This section provides guidance on comparing the results of the PRA with the acceptance guidelines described in Section C.2.4 of this guide. In the context of integrated decisionmaking, the acceptance guidelines should not be interpreted as being overly prescriptive. They are intended to provide an indication, in numerical terms, of what is considered acceptable. The lines between the regions are intentionally blurry to indicate that the NRC has discretion when making licensing decisions involving the risk acceptance guidelines. As such, the numerical values associated with defining the regions in Figures 4 and 5 of this RG are approximate values that provide an indication of the changes that are generally acceptable. Furthermore, the approximate nature of PRA models as discussed below and the state-of-knowledge, or epistemic, uncertainties associated with PRA calculations preclude a definitive decision with respect to the region in which the application belongs based purely on the numerical results.

However, licensees are not granted the same discretion when incorporating these guidelines by reference into other programs (e.g., Technical Specification Task Force (TSTF) Traveler TSTF-505, "Provide Risk-Informed Extended Completion Times - RITSTF Initiative 4b", 10 CFR 50.69). For example, a licensee may use its approved 10 CFR 50.69 program to re-categorize additional systems without prior NRC approval provided that the increase in risk meets the acceptance guidelines in this guide. In this context the licensee needs to treat the guidelines as hard criteria and is not allowed to consider the acceptance guidelines as met when the values are even slightly exceeded.

The intent of comparing the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4 (i.e., proposed increases in CDF or LERF are small and are consistent with the Commission's Safety Goal Policy Statement) is being met. An important point to remember is that a PRA models the continuum of possible plant states in a discrete way, and are, by their very nature, an approximate model of the world. This results in some aspects of the "world" not being addressed except in a bounding way (e.g., different realizations of an accident sequence corresponding to different LOCA sizes, within a category, are treated by assuming a bounding LOCA), with the time of failure of an operating component assumed to occur at the moment of demand. These approximations introduce conservative or non-conservative biases into the results. The degree of conservatism or non-conservatism could in principle be explored by increasing the level of detail in the PRA model, but would typically only be necessary when the decision boundaries are challenged.

As discussed in Section C.2.3.1 the scope of the PRA needed to support a particular application may include several hazard groups or plant operating modes. The process of combining the risk contributions from different hazard groups is sometimes referred to as aggregation. When it is necessary to combine the assessment of the risk implications from different hazard groups, it is important to develop an understanding of the relative level of realism associated with the modeling of each of the hazard groups. For example, the analysis of specific scope items, such as internal fire, internal flooding, or seismic initiating events, typically involves a successive screening approach that allows the detailed analysis to focus on the more significant contributions. The analysis of the less significant contributions is generally of a more conservative nature. In addition, for each of the risk contributors, there are unique sources of model uncertainty. The assumptions made in response to these sources of model uncertainty and any conservatism or non-conservatism introduced by the analysis approach discussed above can bias the results. This is of particular concern for the assessment of importance measures (as contrasted with mean-value risk results) with respect to the combined risk assessment and the relative contributions of the hazard groups to the various risk metrics.

Therefore, this comparison of the PRA results with the acceptance guidelines should be based on an understanding of the contributors to the PRA results; the robustness of the assessment of those contributors, including any conservative or non-conservative biases resulting from modeling assumptions and approximations; and the impacts of the uncertainties, including uncertainties that are explicitly accounted for in the results and those that are not. This is a somewhat subjective process, and the basis for the decisions should be well documented. Section C.2.5.4 of this guide provides guidance on what should be addressed. However, the types of uncertainty that impact PRA results and methods typically used to analyze those uncertainties are briefly discussed first. NUREG-1855 provides acceptable guidance on the treatment of uncertainties in risk-informed decisionmaking.

2.5.1 Types of Uncertainty and Methods of Analysis

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

Because they are generally characterized and treated differently, it is useful to identify three classes of epistemic uncertainty that are addressed in and impact the results of PRAs: parameter uncertainty, model uncertainty, and completeness uncertainty. Completeness uncertainty can be regarded as one aspect of model uncertainty, but because of its importance, it is discussed separately. The following sections summarize the treatment of PRA uncertainty. NUREG-1855 describes the different types of uncertainty and provides acceptable guidance for the treatment of uncertainties in risk-informed decisionmaking. The bibliography may also be consulted for additional information.

2.5.2 Parameter Uncertainty

Each of the models that are used, either to develop the PRA logic structure or to represent the basic events of that structure, has one or more parameters. Typically, each of these models (e.g., the Poisson model for initiating events) is assumed to be appropriate. However, the parameter values for these models are often not known perfectly. Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. They are typically characterized by establishing probability distributions on the parameter values.

These distributions can be interpreted as expressing the analyst's degree of belief in the values these parameters could take, based on his or her state of knowledge and conditional on the underlying model being correct. It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results of the PRA (e.g., CDF, accident sequence frequencies, LERF). However, the analysis should 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 correlation (SOKC) (G. Apostolakis and S. Kaplan, "Pitfalls in Risk Calculations" Ref. 36).

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, CCFs, and reactor coolant pump seal behavior upon a loss of seal cooling. This gives rise to model uncertainty.

In many cases, the appropriateness of the models adopted is not questioned and these models have become, de facto, the consensus models to use. NUREG-1855 defines a consensus model as one that has a publicly available published basis and has been peer reviewed and widely adopted by an appropriate stakeholder group. In addition, widely accepted PRA practices may be regarded as consensus models. Examples of the latter include the use of the constant probability of failure on demand model for standby components and the Poisson model for initiating events. For risk-informed regulatory decisions, the consensus model approach is one that NRC has utilized or accepted for the specific risk-informed application for which it is proposed. For some issues with well-formulated alternative models, PRAs have addressed model uncertainty by using discrete distributions over the alternative models, with the probability associated with a specific model representing the analyst's degree of belief that the model is the most appropriate. A good example is the characterization of the seismic hazard as different hypotheses lead to different hazard curves, which can be used to develop a discrete probability distribution of the initiating event frequency for earthquakes. Other examples can be found in the Level 2 analysis.

Another approach to addressing model uncertainty has been to adjust the results of a single model through the use of an adjustment factor. However it is formulated, an explicit representation of model uncertainty can be propagated through the analysis in the same way as parameter uncertainty. More 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.

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

2.5.4 Completeness Uncertainty

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

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

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

2.5.5 Comparisons with Acceptance Guidelines

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

If the calculated values of ΔCDF and ΔLERF are very small, as defined by Region III in Figures 4 and 5, a detailed quantitative assessment of the base values of CDF and LERF is not 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 need 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 of Figures 4 and 5 in Section C.2.4 to this guide, an assessment of the base values of CDF and LERF is needed.

To demonstrate that the numerical guidelines are met, the level of detail needed for the assessment of the values and the analysis of uncertainty related to model and incompleteness issues depends on both (1) the licensing basis change being considered and (2) the importance of the demonstration that Principle 4 has been met. In Region III of Figures 4 and 5, the closer the ΔCDF or ΔLERF results are to their corresponding acceptance guidelines, the more detail should be provided. Similarly, in Region II of Figures 4 and 5, the closer the ΔCDF or ΔLERF and CDF and LERF results are to their corresponding acceptance guidelines, the more detail should be provided. In a contrasting example, if the value of a particular metric is very small compared to the acceptance guideline, a simple bounding analysis may suffice with no need for a detailed uncertainty analysis.

Because of the way the acceptance guidelines in Section C.2.4 were developed, the appropriate numerical measures to use in the initial comparison of the PRA results to the acceptance guidelines are mean values. The mean values referred to are the means of the probability distributions that result from the propagation of the uncertainties on the input parameters and those model uncertainties explicitly represented in the model. While a formal propagation of the uncertainty is the best way to correctly account for state-of-knowledge uncertainties that arise from the use of the same parameter values for several basic event probability models, under certain circumstances, a formal propagation of uncertainty may not be necessary if it can be demonstrated that the SOKC is unimportant. In the case where it can be demonstrated that the SOKC is unimportant to the regulatory decision under consideration, then the mean value that is quantified without consideration of this correlation can be used. This demonstration involves, for example, a demonstration that the bulk of the contributing scenarios (cut sets or accident sequences) do not involve multiple events that rely on the same parameter for their quantification. Section C.6 of NUREG-1855 provides acceptable guidance on addressing the SOKC.

Consistent with the viewpoint that the guidelines are not to be used prescriptively, even if the calculated ΔCDF and ΔLERF values are such that they place the change in Region I or II, it may be possible to make a case that the application should be treated as if it were in Region II or III if, for example, it is shown that there are unquantified benefits that are not reflected in the quantitative risk results, or if some contributors have been addressed using conservative approaches. However, care should be taken that there are no unquantified detrimental impacts of the proposed licensing basis change, such as an increase in operator burden. In addition, if compensatory measures are proposed to counter the impact of the major risk contributors, such arguments are considered in the decision process quantitatively.

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 base values that need to be quantified, the licensee should 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. In the ASME/ANS standard endorsed by RG 1.200, a reasonable alternative assumption is one that has broad acceptance within the technical community and for which the technical basis for consideration is at least as sound as that of the assumption being made. This demonstration can take the form of well-formulated sensitivity studies or qualitative arguments. It is not the intent that the search for alternatives should be exhaustive or arbitrary. For the decisions that involve only assessing the change in metrics, the number of model uncertainty issues to be addressed should be smaller than for the case of the base values, when only a portion of the model is affected.

The alternatives that would drive the result toward unacceptability 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. Such alternatives are those associated with key sources of model uncertainty, which are defined in the ASME/ANS standard endorsed by RG 1.200 as sources of model uncertainty that could impact the PRA results used in a decision, and consequently, may influence the decision being made. In general, the results of the sensitivity studies should confirm that the guidelines are still met even under the alternative assumptions (i.e., change generally remains in the appropriate region). Alternatively, this analysis can be used to identify candidates for compensatory actions or increased monitoring. Section 8 of NUREG-1855 provides additional, acceptable guidance on treating PRA uncertainty in the decisionmaking process. The licensee should pay particular attention to those assumptions that impact the parts of the model being exercised by the proposed licensing basis 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 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 should be convincing and in some cases may warrant additional PRA analyses. When the margin is significant, a qualitative argument may be sufficient. The contribution of the out-of-scope portions of the model to the change in metric may be addressed by bounding analyses, detailed analyses, or by a demonstration that the change has no impact on the unmodeled contributors to risk. In addition, it should be demonstrated that proposed licensing basis changes based on a partial PRA do not disproportionately change the risk associated with 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 licensing basis change such that the major sources of uncertainty do 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 base CDF or LERF, the proposed change to the licensing basis 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 proposed licensing basis change.

If only a Level 1 PRA is available, in general, only the CDF is calculated and not the LERF. NUREG/CR-6595 presents an approach that allows a subset of the core damage accidents identified in the Level 1 analysis to be allocated to a release category that is equivalent to a LERF. The approach uses simplified event trees that can be quantified by the licensee on the basis of the plant configuration applicable to each accident sequence in the Level 1 analysis. The frequency derived from these event trees can be compared to the LERF acceptance guidelines. The approach described in NUREG/CR-6595 may be used to quantify LERF only in those cases when the plant is not close to the CDF and LERF acceptance guidelines.

The varying levels of detail and conservatisms (and non-conservatisms) in the different hazards and plant operating states need to be considered when combining the results. The impact of these variations on the PRA results can be larger for different risk contributors. However, these concerns do not preclude the combining of results from different risk contributors. The licensee needs to consider the differences in the confidence with which the significant contributors to the risk metric results are representative of the associated risk. Section 4.3 in NUREG-1855 provides additional, acceptable guidance on this issue.

2.6 Integrated Decisionmaking

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

Quantitative risk results from PRA calculations are typically the most useful and complete characterization of risk, but they should be supplemented by qualitative risk insights and traditional engineering analysis where appropriate. Qualitative risk insights include generic results that have been learned from previous PRAs and from operational experience. For example, if one is deciding which motor-operated valves in a plant can be subject to less frequent testing, the plant-specific PRA results can be compared with results from similar plants. This type of comparison can support the licensee's analysis and reduce the staff review of the licensee's PRA. However, as a general rule, applications that affect large numbers of SSCs benefit from quantitative risk assessment.

Traditional engineering analysis provides insight into available margins and defense-in-depth. With few exceptions, these assessments are performed without any quantification of risk. However, a PRA can provide insights regarding the strengths and weaknesses of the plant design and operation relative to defense-in-depth.

The results of the different elements of the engineering analyses discussed in Sections C.2.1 and C.2.2 of this guide should 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 is not driven solely by the numerical results of the PRA. These results are one decisionmaking input and help in building an overall picture of the implications of the proposed licensing basis change on risk. The PRA has an important role in putting the proposed change into its proper context as it impacts the plant as a whole. The PRA analysis is used to demonstrate that Principle 4 has been satisfied. As the discussion in the previous section indicates, both quantitative and qualitative arguments may be brought to bear. Even though the different pieces of evidence used to argue that the principle is satisfied may not be combined in a formal way, they need to be clearly documented.

The acceptability of the proposed licensing basis change supported by the risk-informed decision is 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 proposed 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 are be monitored subsequent to approval. When relying on performance monitoring, the staff should have assurance that the measures truly represent the potential for risk increase and that the criteria are set at reasonable limits. Moreover, one should be sure that degrading performance can be detected in a timely fashion, long before a significant public health issue results. The impact of the monitoring can be fed back into the analysis to demonstrate how it supports the decision.

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

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

Section C.2.4 of this guide indicates that the application would be given increased NRC management attention when the calculated values of the changes in the risk metrics, and their base values, when appropriate, approach the acceptance guidelines. Therefore, if the risk metrics approach or even slightly exceed the acceptance guidelines, the licensee's submittal should address the following issues:

- an identification of the significant contributors to the risk metrics and assessment of the realism with which they have been evaluated, which is particularly important if some contributors are known to have been assessed conservatively or non-conservatively.

- 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 base CDF/LERF are above the guideline values (i.e., 10^{-4} and 10^{-5} per reactor year, respectively).

3. Element 3: Define Implementation and Monitoring Program

Careful consideration should be given to implementation of the proposed change and the associated performance-monitoring strategies. The primary goal of Element 3 is to ensure that no unexpected adverse safety degradation occurs due to the change(s) to the licensing basis. 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 ensures that the conclusions that have been drawn from the evaluation remain valid. Application-specific RGs (RG 1.177, RG 1.178, and RG 1.201) discuss additional details of acceptable processes for implementation in specific applications.

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

The licensee should 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 licensing basis. The program should be capable of trending equipment performance after a change has been implemented to demonstrate that performance is consistent with the assumptions in the traditional engineering and probabilistic analyses conducted to justify the change. This may include monitoring associated with nonsafety-related SSCs if the analysis determines that those SSCs are risk significant. The program should be structured such that (1) SSCs are monitored commensurate with their safety importance (i.e., monitoring for SSCs categorized as having low safety significance may be less rigorous than that for SSCs of high safety significance), (2) feedback of information and corrective actions is accomplished in a timely manner, and (3) degradation in SSC performance is detected and corrected before plant safety can be compromised. The potential impact of observed SSC degradation on similar components in different systems throughout the plant should be considered.

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

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

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

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

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

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

As part of the monitoring program, it is important that provisions for specific cause determination, trending of degradation and failures, and corrective actions be included. Such provisions should be applied to SSCs commensurate with their importance to safety as determined by the engineering evaluation used to support the licensing basis change. A determination of cause is needed when performance expectations are not being met or when there is a functional failure of an application-specific SSC that poses a significant condition adverse to performance. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or ensure that it is anticipated before becoming a safety concern. It should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common-cause implications as defined in NUREG/CR-5485, "Guidance on Modeling Common-Cause Failures in Probabilistic Risk Assessment" (Ref. 37).

Finally, in accordance with Criterion XVI of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (Ref. 38), the monitoring program should identify any corrective actions to preclude the recurrence of unacceptable failures and/or degraded performance. The circumstances surrounding the failure may indicate that the SSC failed because of adverse or harsh operating conditions (e.g., operating a valve dry, over-pressurization of a system) or failure of another component that caused the SSC failure. Therefore, corrective actions should also consider SSCs with similar characteristics with regard to operating, design, or maintenance conditions. The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

4. Element 4: Submit Proposed Change

Requests for proposed changes to the plant's licensing basis typically take the form of requests for license amendments (including changes to or removal of license conditions), technical specification changes, changes to or withdrawals of orders, and changes to programs under 10 CFR 50.54, "Conditions of Licenses" (Ref. 39) (e.g., quality assurance program changes under 10 CFR 50.54(a)). Licensees should (1) carefully review the proposed licensing basis change to determine the appropriate form of the change request; (2) ensure that information required by the relevant regulations in support of the request is developed; and (3) prepare and submit the request in accordance with relevant procedural requirements. For example, license amendments should meet the requirements of 10 CFR 50.90, 10 CFR 50.91, "Notice for Public Comment; State Consultation" (Ref. 40), and 10 CFR 50.92, as well as the procedural requirements in 10 CFR 50.4, "Written Communications" (Ref. 41). Risk information that the licensee submits in support of the licensing basis change request should meet the guidance in Section C.6 of this RG.

Licensees may submit risk information in support of their licensing basis change request. If the licensee's proposed change to the licensing basis is consistent with currently approved staff positions, the staff's determination is generally 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 considers information based on both traditional engineering analyses and risk insights. If the licensee does not submit risk information in support of a licensing basis 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 reviews the proposed application using traditional engineering analyses and determines 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 change that may substantially increase risk, the NRC staff requests that the licensee submit risk-related information. The NRC staff will not approve the requested licensing basis change until it has reasonable assurance that the public health and safety will be adequately protected if the requested licensing basis change is approved.

In developing the risk information set forth in this RG, licensees are likely to identify SSCs with high risk significance that are not currently subject to regulatory requirements or are subject to a level of regulation that is not commensurate with their risk significance. As such, licensees should propose licensing basis changes that would subject these SSCs to an appropriate level of regulatory oversight, consistent with the risk significance of each SSC. Application-specific RGs (RG 1.177, RG 1.178, and RG 1.201) present specific information on the staff's expectations in this regard.

5. Quality Assurance

As stated in Section C.2 of this guide, the engineering analyses conducted should justify proposed licensing basis changes are appropriate for the nature of the change. In this regard, it is expected that for traditional engineering analyses (e.g., deterministic engineering calculations), existing provisions for quality assurance (e.g., Appendix B to 10 CFR Part 50, for safety-related SSCs) will apply and provide the appropriate quality needed. Likewise, when a risk assessment of the plant is used to provide insights into the decisionmaking process, the PRA is to have been subject to quality control.

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

- Use personnel qualified for the analysis.

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

- Provide documentation and maintain records in accordance with the guidelines in Section C.6 of this guide.

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

When performance monitoring programs are used in the implementation of proposed changes to the licensing basis, those programs should 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 licensing basis change, provided it can be shown that the appropriate quality provisions are met.

6. Documentation

6.1 Introduction

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

6.2 Archival Documentation

Archival documentation should include a detailed description of engineering analyses conducted and the results obtained, irrespective of whether they were quantitative or qualitative, or whether the analyses made use of traditional engineering methods or probabilistic approaches. This documentation should be maintained by the licensee, as part of its quality assurance program, so that it is available for examination. Documentation of the analyses conducted to support changes to a plant's licensing basis should be maintained as lifetime quality records in accordance with RG 1.33, "Quality Assurance Program Requirements (Operation)" (Ref. 42).

6.3 Licensee Submittal Documentation

To support the NRC staff's conclusion that the proposed licensing basis change is consistent with the key principles of risk-informed regulation and NRC staff expectations, the licensee should submit the following information:

- A description of how the proposed change impacts the licensing basis. This relates to the risk-informed decisionmaking principle that the licensing basis 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. The staff expectation is that all safety impacts of the proposed licensing basis change should be evaluated.

- A reevaluation of the licensing basis accident analysis and the provisions of 10 CFR Part 20, "Standards for Protection against Radiation" (Ref. 43), and 10 CFR Part 100, "Reactor Site Criteria" (Ref. 44), if appropriate. This relates to the risk-informed decisionmaking principles of the licensing basis changes meeting the regulations, sufficient safety margins are maintained, and consistency with the defense-in-depth philosophy is maintained.

- An evaluation of the impact of the licensing basis change on the breadth or depth of defense-in-depth attributes of the plant. This relates to the risk-informed decisionmaking principle that the proposed licensing basis change maintains consistency with the defense-in-depth philosophy.

- Identification of how and where the proposed change will be documented as part of the plant's licensing basis (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. As defined in the ASME/ANS standard endorsed in RG 1.200, an assumption is labeled "key" when it may influence (i.e., have the potential to change) the decision being made.

- SSCs for which requirements should be increased.

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

- Whether provisions of Appendix B to 10 CFR Part 50 apply to the PRA.

The latter item comes into play if the PRA forms part of the basis used to enhance or modify safety-related functions of SSCs subject to those provisions. Thus, the licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis and in accordance with all applicable regulations and its quality assurance program description.

An independent peer review (as described in RG 1.200) is important in ensuring PRA acceptability. The licensee's submittal should discuss measures used to ensure the PRA is acceptable for the application PRA, such as a report of a peer review augmented by a discussion of the appropriateness of the PRA model for supporting a risk assessment of the licensing basis change under consideration. The submittal 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 should also be submitted. For example, this response could indicate whether the PRA was modified following the peer review or could justify why no change was necessary to support decisionmaking for the licensing basis change under consideration. As discussed in Section C.2.2 of this guide, the staff's decision on the proposed license amendment is based on its independent judgment and review.

6.3.1 Risk Assessment Methods

To have confidence in the risk assessment used support the proposed change, a summary of the risk assessment methods used should be submitted. Consistent with current practice, information submitted to the NRC for its consideration in making risk-informed regulatory decisions will be made publicly available, unless such information is properly identified as proprietary in accordance with the regulations. The following information should be submitted and is intended to illustrate that the engineering analyses conducted to justify the proposed licensing basis change are appropriate to the nature and scope of the change:

- A description of risk assessment methods used.

- Documentation showing that the base PRA is acceptable.

- A description of the licensee's process to ensure PRA acceptability and a discussion as to why the PRA is acceptable to support the current application.

- The key modeling assumptions that are necessary to support the analysis or that impact the application. A modeling assumption is one that is related to a model uncertainty and is made with the knowledge that a different reasonable alternative assumption exists. A reasonable alternative assumption is one that has broad acceptance within the technical community and for which the technical basis for consideration is at least as sound as that of the assumption being made. An assumption is considered "key" when it may influence (i.e., have the potential to change) the decision being made. NUREG-1855 provides useful insights related to this expectation.

- The event trees and fault trees that require modification to support analyses of the proposed change with a description of their modification.

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

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

- The effects of the proposed change on the more significant sequences (e.g., sequences that contribute more than five percent to the risk) to show that the licensing basis 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 and an assessment of the realism with which those contributors have been evaluated.

- Information related to the assessment of the full-scope, base CDF; the extent of the information needed depends on whether the analysis of the change in CDF is in Region II or Region III of Figure 4.

- Information related to the assessment of the full-scope, base LERF; the extent of the information needed depends on whether the analysis of the change in LERF is in Region II or Region III of Figure 5.

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

6.3.2 Cumulative Risks

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

As part of the submittal, the licensee should track and submit the impact of all plant changes that have been submitted for NRC review and approval which have not yet been incorporated into the base PRA model, and are therefore not reflected in the base risk. Documentation should include the following:

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

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

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

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

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

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees[2] may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting" and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Applicants and Licensees

Applicants and licensees may voluntarily[3] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

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

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

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised RG and (2) the specific subject matter of this RG is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this RG or provide an equivalent alternative process that demonstrates compliance with the

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

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

underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

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

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 45), and NUREG-1409, "Backfitting Guidelines" (Ref. 46).

REFERENCES[4]

1. *U.S. Code of Federal Regulations* (CFR), "Domestic Licensing of Production and Utilization Facilities," Part 50, Chapter 1, Title 10, "Energy"

2. CFR, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Part 52, Chapter 1, Title 10, "Energy"

3. CFR, "Application of amendment of license, construction permit or early site permit," Part 50, Chapter 1, Title 10, Section 50.90, "Energy"

4. CFR, "Issuance of amendment," Part 50, Chapter 1, Title 10, Section 50.92, "Energy"

5. U.S. Nuclear Regulatory Commission (NRC), NUREG-0800, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," Section 19.2, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance," Washington, DC.

6. NRC, RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," Washington, DC.

7. NRC, NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking," Washington, DC.

8. NRC, Staff Requirements Memorandum (SRM) on SECY-11-0014, "Staff Requirements – SECY-11-0014 – Use of Containment Accident Pressure in Analyzing Emergency Core Cooling System and Containment Heat Removal System Pump Performance in Postulated Accidents," Washington, DC, March 15, 2011. (ADAMS Accession No. ML110740254)

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11. CFR, "Backfitting," Part 50, Chapter 1, Title 10, Section 50.109, "Energy"

12. CFR, "Specific exemptions," Part 50, Chapter 1, Title 10, Section 50.12, "Energy"

13. CFR, "Changes, tests and experiments," Part 50, Chapter 1, Title 10, Section 50.59, "Energy"

[4] Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

14. NRC, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," *Federal Register*, Vol. 51, pp. 30028, (51 FR 30028), Washington, DC, August 4, 1986.

15. International Atomic Energy Agency (IAEA), Safety Guide SSG-3, "Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," Vienna, Austria, 2010.[5]

16. IAEA Safety Guide SSG-4, "Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants Specific Safety Guide," Vienna, Austria, 2010.

17. IAEA Safety Standards SSR-2/1, "Safety of Nuclear Power Plants: Design," Vienna, Austria, 2012.

18. IAEA Safety Standard SF-1, "Fundamental Safety Principles," Vienna, Austria, 2006.

19. NRC, NUREG/KM-0009, "Historical Review and Observations of Defense-in-Depth," Washington, DC.

20. NRC, NUREG/CR-6595, "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," Washington, DC.

21. NRC, SRM on SECY-12-0081, "Staff Requirements – Secy-12-0081 – Risk-Informed Regulatory Framework for New Reactors," Washington, DC, October 22, 2012. (Agencywide Document Access and Management System (ADAMS) Accession No. ML12296A158)

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26. CFR, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," Part 50, Chapter 1, Title 10, Section 50.69, "Energy"

[5] Copies of IAEA documents may be obtained through their Web site: www.iaea.org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria.

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30. NRC, RG 1.216, “Containment Structural Integrity Evaluation for Internal Pressure Loadings above Design-Basis Pressure,” Washington, DC.

31. NRC, RG 1.175, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing,” Washington, DC.

32. NRC, RG 1.177, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications,” Washington DC.

33. NRC, RG 1.178, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping,” Washington, DC.

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APPENDIX A

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

A-1. Introduction

For several of the proposed applications of the risk-informed regulation process, one of the principal activities is the categorization of structures, systems, and components (SSCs) and human actions according to safety significance. The purpose of this appendix is to discuss one way that this categorization may be performed to be consistent with Principle 4 (see Figure 2 of Regulatory Guide (RG) 1.174) and the expectations discussed in Section C.2.1 of this RG.

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 RG 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 of SSCs with respect to safety significance, it is important to recognize the purpose behind the categorization, which is to sort the SSCs and human actions into groups (e.g., those for which some relaxation of requirements is proposed and those for which no such change is proposed). The proposed application motivates 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 should be regarded as safety significant within the context of the application. This impact on overall risk should be evaluated in light of the principles and decision criteria identified in this guide. Thus, the most appropriate way to address the categorization is through a requantification of the risk measures.

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

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

In the implementation of the Maintenance Rule (Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.65, “Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants”) and in industry guides for risk-informed applications (e.g., the “PSA Applications Guide”) (Ref. 47), the Fussell-Vesely Importance, Risk Reduction Worth, and Risk Achievement Worth are the most commonly identified measures in the relative risk ranking of SSCs. However, in using these importance measures for risk-informed applications, there are several issues that should be addressed. Most of the issues are related to technical problems that can be resolved by the use of sensitivity studies or by appropriate quantification techniques. These issues are discussed in detail below. In addition, the licensee should be aware of and adequately address two other issues: (1) that risk rankings apply only to individual contributions and not to combinations or sets of contributors and (2) that risk rankings are not necessarily related to the risk changes that result from those contributor changes. When performed and interpreted correctly, component-level importance measures can provide valuable input to the licensee.

Risk-ranking results from a PRA can be affected by many factors, the most important being model assumptions and techniques (e.g., for modeling of human reliability or common-cause failures (CCFs)), the data used, or the success criteria chosen. The licensee should therefore make sure that the PRA is acceptable, consistent with the guidance in this guide and in RG 1.200.

In addition to the use of an 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 below.

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

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

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

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

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

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

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

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

In the absence of appropriately defined group-level importance measures, the appropriate determination should rely on a qualitative categorization by the licensee, as part of the integrated decisionmaking process.

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

SSCs Not Included in the Final Quantified Cut Set Solution: Importance measures based on the quantified cut sets should 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 should ensure that these SSCs are considered.