Attachment 1

FRAMEWORK FOR RISK-INFORMED CHANGES TO THE TECHNICAL REQUIREMENTS OF 10 CFR 50

Draft, Revision 2

Prepared by
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications
Probabilistic Risk Analysis Branch

Tom King
Mark Cunningham
Mary Drouin
Alan Kuritzky

Sandia National Laboratories
Allen Camp
Jeff LaChance

ERI Consulting
Eric Haskin

Brookhaven National Laboratory
John Lehner
Vinod Mubayi
Trevor Pratt

August 2000

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

1.0 INTRODUCTION

1.1 Background

The NRC's policy statement on probabilistic risk assessment (PRA) encourages greater use of PRA to improve safety decision making and regulatory efficiency (Ref. 1). The NRC has undertaken a number of activities to risk-inform regulations and regulatory processes in order to enhance safety and reduce unnecessary burden.

In SECY-98-300, (Ref. 2) the NRC staff presented the following three options for applying PRA insights to risk-inform existing regulatory requirements in 10 CFR Part 50:

1. Continue ongoing rulemaking activities and risk-informed approaches making no changes to the current Part 50 (Option 1),

2. Change the special treatment rules in Part 50 to modify their scope to be risk-informed, (Option 2), and

3. Make changes to specific requirements in the body of the regulations, including the general design criteria (Option 3).

In a June 8, 1999 Staff Requirements Memorandum (SRM), the Commission approved proceeding with the current rulemakings in Option 1, implementing Option 2, and proceeding with a study of Option 3.

SECY-99-264 (Ref. 3) provides the NRC staff's plan for the study phase of its efforts under Option 3 to risk-inform the technical requirements of 10 CFR 50. The plan consists of two phases:

1. An initial study phase (Phase 1) where recommendations to the Commission on proposed changes will be made, and

2. An implementation phase (Phase 2) where changes recommended in Phase 1 and approved by the Commission will be made.

1.2 Objectives

In SECY-98-300, the staff delineated the following broad objectives for its work to risk-inform 10 CFR Part 50:

- Enhance safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety,

- Provide NRC with the framework to use to risk information to take action in reactor regulatory matters, and

- Allow use of risk information to provide flexibility in plant operation and design, which can result in burden reduction without compromising safety.

The possible approaches to revising the existing body of regulations under Option 3 include:

- adding provisions to Part 50 allowing the staff to approve risk-informed alternatives to current regulations

- revising specific requirements to reflect risk-informed considerations, and

- deleting unnecessary or ineffective regulations.

The objective of this document is to present a framework that will be used by the NRC staff to guide the development of risk-informed alternative regulations under Option 3. The risk-informed alternatives developed under Option 3 would be voluntary alternatives to current requirements.

1.3 Scope and Limitations

The framework presented herein is a risk-informed defense-in-depth approach, which provides guidance to the NRC staff for its initial efforts to develop risk-informed alternatives to existing regulations (sections of 10 CFR 50) under Option 3. The emphasis is on regulations that impact existing plants. Licensees will have the option to comply with all of the requirements of an existing regulation or with all of the requirements of a risk-informed alternative regulation.

It is anticipated that this framework will continue to evolve as experience is gained in developing risk-informed alternatives. The current guidance is directed toward existing regulations that have an impact on prevention or mitigation of core-damage accidents, because these accidents present the most risk to the public and risk information is most prevalent for such accidents. In the future, the framework can be adapted and extended to apply to regulatory requirements that impact non-core-damage accidents.

The framework is generally consistent with the Regulatory Analysis Guidelines (Ref. 4) and Regulatory Guide 1.174 (Ref. 5). The Regulatory Analysis Guidelines focus on regulatory changes that would decrease risk but impose additional burden. Regulatory changes of this type that are identified under Option 3 and have the potential to pass the backfit rule will be referred to the Generic Safety Issues program to assess the need for mandatory implementation.

Like Regulatory Guide 1.174, the framework also addresses changes that could result in risk increases. Regulatory Guide 1.174, provides guidance to licensees requesting changes to an individual plant's licensing basis. Risk increases associated with such licensee-proposed changes are appropriately evaluated relative to the existing plant risk. An alternative regulation developed under Option 3 will apply to all plants that choose to comply with the alternative rather than the existing regulation. Accordingly, in Option 3 as in the Regulatory Analysis Guidelines, the potential industry-wide risk impact of changes made to comply with alternative risk-informed regulations must be assessed.

Option 2 involves making changes to the overall scope of systems, structures and components (SSCs) covered by those sections of Part 50 requiring special treatment (such as quality assurance, environmental qualification, etc.). Alternative regulations developed in the Option 3 study will reflect the experience gained in Option 2 classification efforts. When possible, approaches that are consistent with Option 2 will be included in risk-informed regulations developed under Option 3.

1.4 Approach

Section 2 describes the risk-informed defense-in-depth approach, which builds on the cornerstones of safe nuclear power operation contained in the Reactor Inspection and Oversight Program. Because the initial focus of the Option 3 efforts is on regulations that impact prevention and mitigation of accidents involving the reactor core, the defense-in-depth strategies are tied to the four reactor safety cornerstones.

Section 3 presents the quantitative guidelines for the framework. These quantitative guidelines will be used by the NRC staff in identifying existing regulations that are candidates for risk-informed change, formulating and evaluating change options, and recommending the changes to be included in alternative, risk-informed regulations.

The quantitative guidelines are not proposed regulatory requirements and will generally not appear in risk-informed regulations; however, they may appear in implementing documents such as regulatory guides when probabilistic analyses are deemed appropriate.

In applying the quantitative guidelines risk increases are only permitted if they are reasonable relative to the Quantitative Health Objectives of the Safety Goal Policy Statement (Ref. 6), and then only they are consistent with the overall defense-in-depth approach. The quantitative guidelines are not proposed regulatory requirements and will generally not appear in risk-informed regulations; however, they may appear in implementing documents such as regulatory guides when probabilistic analyses are deemed appropriate. This reflects an important choice. In theory, one could develop and apply a more generous regulatory framework, one that permits the elimination of all measures not needed for adequate protection (that level of protection of the public health and safety that must be reasonably assured regardless of economic cost). Like the Regulatory Analysis Guidelines and Regulatory Guide 1.174, the framework presented here takes a more restrictive approach. This approach is taken to compensate for PRA limitations and uncertainties, including completeness uncertainty. Safety issues continue to emerge notwithstanding the maturity of the nuclear power industry. Treatment of uncertainties is in Section 4.

Implementation of the framework in the Phase 1 study is described in Section 5. The staff will identify and prioritize candidate regulations for risk-informed changes. If risk information indicates possible holes in existing regulations, these will also be considered. A risk-informed alternative to the technical requirements of a rule will be developed using the framework (as described in Section 5) and recommended to the Commission for approval. This risk-informed alternative will be based on sufficient analysis to show its feasibility. With Commission approval, more detailed regulatory analyses of recommended alternatives will be performed under Phase 2.

2.0 DEVELOPMENT OF THE FRAMEWORK

2.1 Overview

Figure 2-1 illustrates the key elements of the framework. The primary goal is to protect the public health and safety. The framework constitutes a risk-informed, defense-in-depth approach. It will be used by the NRC staff to analyze the effectiveness of existing regulations in supporting the primary goal. When the staff determines that the effectiveness of an existing regulation can be improved, an alternative risk-informed regulation, which is consistent with the framework, is formulated and recommended to the Commission.

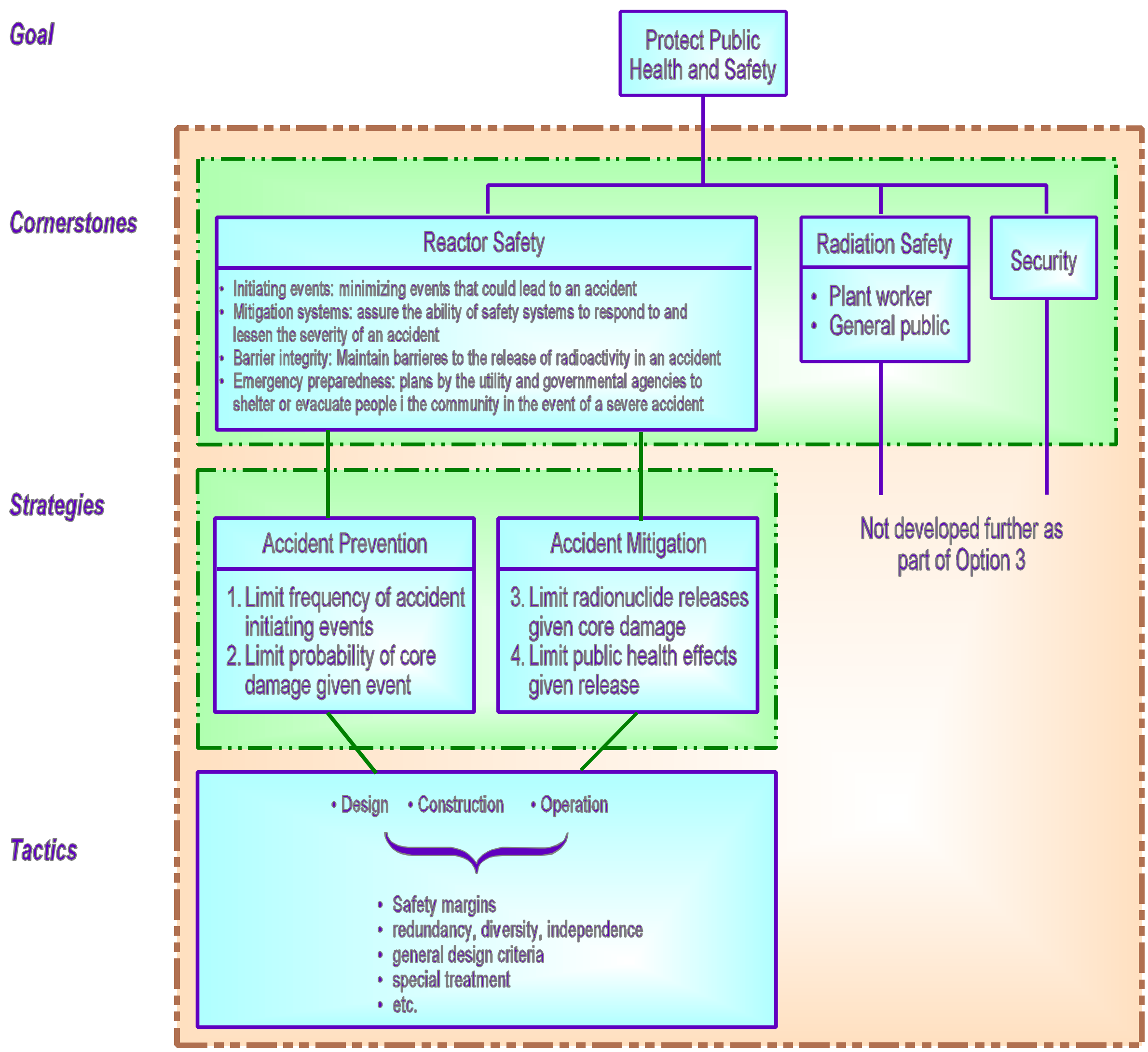

Figure 2-1 Risk-Informed Defense-in-Depth Framework.

The elements of the risk-informed defense-in- depth approach are discussed in Section 2.2. As indicated in Figure 2-1, this approach is consistent with cornerstones of safe nuclear power plant operations, which were identified in the NRC Reactor Inspection and Oversight Program (Ref. 7). Specific strategies and related elements of the framework are used to implement the cornerstones as discussed in the following sections. Quantitative guidelines are developed in Chapter 3.

2.2 Defense-in-Depth Approach

The term defense-in-depth is used to describe applications of multiple measures to prevent or mitigate accidents. The measures can be embodied in SSCs or in procedures (including emergency plans). Defense-in-depth can be applied in various ways. Redundant or diverse means may be used to accomplish a function, the classic example being the use of multiple barriers (fuel, cladding, reactor coolant pressure boundary, spray or scrubbing systems, and containment) to limit the release of core radionuclides. Alternatively, redundant or diverse functional lines of defense may be used to accomplish a goal.

To illustrate, consider the primary goal of protecting the public from nuclear power plant accidents. As indicated in Figure 2-1, the first line of defense is to eliminate initiators that could conceivably lead to core damage. However, it is not possible to eliminate all initiators. The frequency of initiators, although significantly less than before the accident at Three Mile Island Unit 2 (TMI-2), is about 1 per plant year. As a second line of defense, systems such as the Emergency Core Cooling System (ECCS) are provided to prevent core damage should postulated initiators occur. Although such systems are designed for a wide spectrum of initiators and compounding equipment failures, no prevention system is perfect. As a third line of defense, barriers including containment and associated heat and fission product removal systems are required. These barriers would prevent large radionuclide releases for many severe accidents, but scenarios exist in which containment would be breached or bypassed. A fourth line of defense, offsite emergency preparedness, is therefore required.

Defense-in-depth has evolved since the first research reactors were designed in the 1940s. In a recent letter to the NRC Chairman, the Advisory Committee on Reactor Safeguards (ACRS) discusses this evolution, identifies two schools of thought on the scope and nature of defense-in-depth, and recommends an approach for moving forward with risk-informed regulation (Ref. 8),(Ref. 9). The two schools of thought (models) of defense-in-depth are labeled "structuralist" and "rationalist," but they could just as well be labeled "traditionalist" and "risk-based."

The structuralist or traditionalist model asserts that defense-in-depth is embodied in the structure of the regulations and in the design of the facilities built to comply with those regulations. Defense-in-depth requirements are derived by repeated application of the question, "What if this barrier or safety feature fails?" The results of that process are documented in the regulations themselves, specifically in Title 10 of the Code of Federal Regulations.

In contrast, the rationalist (or risk-based) model asserts that defense-in-depth is the aggregate of provisions made to compensate for uncertainty and incompleteness in our knowledge of accident initiation and progression. This is made practical by the ability to quantify risk and estimate uncertainty using PRA methods.

What distinguishes the rationalist model from the structuralist model is the degree to which the rationalist model depends on establishing quantitative safety goals and carrying formal probabilistic analyses, including analyses of uncertainties, as far as the analytical methodology permits. In the rationalist model, the exercise of engineering judgement, to determine the kind and extent of defense-in-depth measures, occurs after the capabilities of the analyses have been exhausted.

The approach adopted herein recognizes the relevance of both structuralist and risk-based considerations. From a structuralist viewpoint, the approach requires accident prevention and mitigation strategies and supporting elements. Reflecting the rationalist view, probabilistic insights are used in implementing the required strategies and elements. The approach used in Option 3 is summarized in the following working definition:

Defense-in-depth is the approach taken to protect the public by applying the following strategies in a risk-informed manner:

1. *limit the frequency of accident initiating events*

2. *limit the probability of core damage given accident initiation*

3. *limit radionuclide releases during core damage accidents*

4. *limit public health effects due to core damage accident*

The strategies consider the following defense-in-depth elements:

- *reasonable balance is provided among the strategies (as shown in Figure 3-1).*

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

- *independence of barriers is not degraded.*

- *safety function success probabilities commensurate with accident frequencies, consequences, and uncertainties are achieved via appropriate*
  - *redundancy, independence, and diversity,*
  - *defenses against common cause failure mechanisms,*
  - *defenses against human errors, and*
  - *safety margins*

- *the defense-in-depth objectives of the current General Design Criteria (GDCs) in Appendix A to 10 CFR 50 are maintained.*

The four strategies emphasizes defense against core damage accidents, which dominate the risk to public health and safety posed by existing plants. Quantitative guidelines are developed in Chapter 3 to characterize a reasonable balance among the preventive and mitigative strategies. For risk significant accidents in which one or more of the four strategies are precluded (e.g., containment bypass accidents), the remaining strategies may be more tightly regulated; that is, regulations should provide a very high confidence in the remaining strategies. Similarly, more stringent requirements may be imposed in the presence of large uncertainties regarding the effectiveness of one of the strategies.

The supporting elements specifically listed in the working definition have, with the addition of safety margin, been adapted from the defense-in-depth elements listed in Regulatory Guide 1.174. The importance of the supporting elements in the presence of uncertainties, in particular the use of safety margin, is discussed in Section 4.

As indicated by the final element of the working definition, effective practices are preserved. Emergency planning will be maintained to support the fourth strategy. Requirements that fuel design limits not be exceeded in anticipated operational occurrences (AOOs) and that the extent of fuel damage be limited in design basis accidents (DBAs) will be maintained. Preserving an effective practice does not preclude developing risk-informed changes to the practice. For example, risk insights will likely be used to identify alternative, risk-informed DBAs to be analyzed. Similarly, risk-informed changes to GDCs are not precluded. For example, it has been suggested that a number of requirements related to fuel design limits during normal operation could be eliminated because their intent is being met for commercial reasons, and the requirements are not risk significant. Also, the risk significance of failure events prescribed for DBAs in the GDCs will be evaluated based on PRA insights.

2.3 Cornerstones and Strategies

In the process of developing risk-informed improvements to the NRC Reactor Inspection and Oversight Program (Ref. 10), general agreement was reached with the nuclear industry and the public regarding the following cornerstones of safe nuclear power plant operations:

Reactor Safety Cornerstones

1. Initiating Events - Minimizing events that could lead to an accident

2. Mitigation Systems - Assure the ability of safety systems to respond to and lessen the severity of an accident

3. Barrier Integrity - Maintain barriers to the release of radioactivity in an accident

4. Emergency Preparedness - Plans by the utility and governmental agencies to shelter or evacuate people in the community in the event of a severe accident

Radiation Safety Cornerstones

5. Plant Worker - Minimize exposure during routine operations

6. General Public - Provide adequate protection during routine operations

Security Cornerstone

7. Physical protection of plant and nuclear fuel

The four reactor safety cornerstones are directly addressed in PRAs and are, therefore, most relevant to the initial Option 3 efforts. As illustrated in Figure 2-1, the four reactor safety cornerstones are reflected in the framework by the four defense-in-depth strategies. The strategies seek both to prevent core damage accidents and to mitigate the public impact should a core damage accident occur. The two preventive strategies are:

- limit the frequency of accident initiating events (initiators), and

- limit the probability of core damage given accident initiation.

The two mitigative strategies are:

- limit radionuclide releases during core damage accidents, and

- limit public health effects due to core damage accidents.

Except for the implied emphasis on core damage accidents, Strategy 1 is identical to Reactor Safety Cornerstone 1. Similarly, for core damage accidents, Strategy 4 is equivalent to Reactor Safety Cornerstone 4, and Strategies 2 and 3 are functionally equivalent to Reactor Safety Cornerstones 2 and 3.

The four defense-in-depth strategies are intentionally more focused than the reactor safety cornerstones. The cornerstones also apply to accidents that can not lead to core damage (for example fuel-handling, fuel-storage, and radwaste storage tank rupture accidents). The strategy statements may in the future be modified to address non-core-damage accidents; however, emphasis on core damage accidents is appropriate for the initial efforts to risk-inform existing regulatory requirements.

The radiation safety and security cornerstones are part of the overall approach, but generally secondary considerations in making risk-informed changes to the existing regulatory requirements. This is because they are not well-treated in probabilistic risk assessments.

In describing the cornerstones and strategies, the words “limit,” “prevent,” and “contain” are relative rather than absolute. Cutting a failure rate in half "prevents" half the failures that would otherwise occur in a given time period, and some fixes last for the life of a plant. However, it is not possible to prevent all accident initiators or to eliminate the possibility of core damage or containment failure for all conceivable accidents. All four strategies are applied to compensate for the limitations of the individual strategies; issues related to PRA scope, level of detail, and technical adequacy; and uncertainty, in particular completeness uncertainty.

2.4 Other Framework Elements

As indicated in Figure 2-1, other elements are applied to support the cornerstones and related strategies. These elements are referred to as tactics to distinguish them from the four defense-in-depth strategies. Existing regulatory requirements apply a wide variety of tactics. Some tactics such as quality assurance are broadly applicable to all four strategies. Other tactics, are used to address a particular type of concern. Safety margin is often applied to provide a high degree of confidence that a design or process will provide a needed function. (Safety margin is discussed further in Section 4.) Other tactics may only be applicable to specific strategies or accident types. No attempt is made to present a comprehensive list of tactics. Assessing which, if any, tactics are required to support a given regulation is part of the Option 3 study. The primary responsibility for implementing tactics, whether required by regulations or not, resides with the licensee.

The single failure criterion is a tactic that is to be examined in the Option 3 study. Specifically, "the conditions under which a single failure of a passive component in a fluid system should be considered in designing the system" have yet to be developed (10 CFR 50 Appendix A). Insights from probabilistic risk assessments regarding the risk significance of passive single failures in fluid systems will be reviewed, and options for resolving this issue will be delineated consistent with the quantitative guidelines developed in Section 3.

3.0 QUANTITATIVE GUIDELINES FOR THE FRAMEWORK

Quantitative guidelines for the preventive and mitigative defense-in-depth strategies are developed in this section. These guidelines are applied by the NRC staff to assess the effectiveness of existing regulations, to formulate and compare risk-informed options to existing regulatory requirements, and to develop risk-informed alternative regulations.

In the context of integrated decisionmaking, the acceptance guidelines should not be interpreted as being overly prescriptive. The quantitative guidelines are not proposed regulatory requirements. They reflect a desired level of safety against which to compare industry-averaged risk measures; a level that is "safe enough" based on the Commission's Safety Goal Policy Statement while providing reasonable balance among the defense-in-depth strategies.

As a starting point for developing quantitative guidelines, consider the Quantitative Health Objectives (QHOs), which were originally set to as a measure of "safe enough":

- "The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accident to which members of the U.S. population are generally exposed."

- "The risk to the population in the area of nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes."

These QHOs have been translated into two numerical objectives, as follows:

- The individual risk of a prompt fatality from all "other accidents to which members of the U.S. population are generally exposed," such as fatal automobile accident, etc., is about $5x10^{-4}$ per year. One-tenth of one percent of this figure implies that the individual risk of prompt fatality from a reactor accident should be less than $5x10^{-7}$ per reactor year (ry). The "vicinity" of a nuclear power plant is understood to be a distance extending to 1 mile from the plant site boundary. The "average" individual risk is determined by dividing the number of prompt or early fatalities (societal risk) to 1 mile due to all accidents, weighted by the frequency of each accident, by the total population to 1 mile and summing over all accidents.

- "The sum of cancer fatality risks resulting from all other causes" is taken to be the cancer fatality rate in the U.S. which is about 1 in 500 or $2x10^{-3}$ per year. One-tenth of one percent of this implies that the risk of cancer to the population in the area near a nuclear power plant due to its operation should be limited to $2x10^{-6}$/ry. The "area" is understood to be an annulus of 10-mile radius from the plant site boundary. The cancer risk is also determined on the basis of an "average individual," i.e., by evaluating the number of latent cancers (societal risk) due to all accidents to a distance of 10 miles from the plant site boundary, weighted by the frequency of the accident, dividing the total population to 10 miles, and summing over all accidents.

Unfortunately, the QHOs are difficult to apply in making risk-informed changes to the existing regulations. PRAs often do not proceed to Level 3, that is, to the quantification of public health risks and even if they did, their calculation is dependent upon many factor outside the licensee's control (e.g., population density).

In addition, simply replacing existing existing regulations with the QHOs would not be risk-informed. It would not assure reasonably balanced defense-in-depth approach. To illustrate, consider the following example. Even at a densely populated U.S. site, if a plant's core damage frequency is 10^{-4} per year or less, the latent cancer QHO is generally met with no credit taken for containment. The early fatality QHO is more restrictive than the latent cancer QHO. If a plant's large early release frequency is 10^{-5}/yr or less, the early fatality QHO is generally met. Conceivably, both QHOs could be met by reducing a plant's CDF to 10^{-5}/yr or less with no containment and no preplanned offsite protection actions. This would not constitute a risk-informed approach.

What is required for a risk-informed approach are quantitative measures and guidelines that can be used to describe and indicate the effectiveness of the defense-in-depth strategies. The measures and guidelines proposed for this purpose are summarized in Figure 3-1. They are generally consistent with those in current use (e.g., (Ref. 11)(Ref. 12)).

Figure 3-1 Quantitative Guidelines for Risk-Informed Changes to Regulatory Requirements.

	Accident Prevention		Accident Mitigation	
	Core Damage Frequency $\leq 10^{-4}$/year		Conditional Large Early Release Probability $\leq 10^{-1}$ (Note 5)	
	Limit frequency of accident initiating events	Limit probability of core damage given event	Limit radionuclide releases given core damage	Limit public health effects given release
	Initiator Frequency	Conditional core damage probability	Conditional large early release probability	Conditional Individual fatality probability
Frequent initiators	≥ 1/year	$\leq 10^{-4}$	$\leq 10^{-1}$	Note 3
Infrequent initiators	$\leq 10^{-2}$/year	$\leq 10^{-2}$	$\leq 10^{-1}$	Note 3
Rare initiators	$\leq 10^{-5}$/year	Note 4	Note 4	Note 3

Notes:
1. The product across each row gives a large early release frequency of $<10^{-5}$/year.
2. It is preferable that no single type of initiator cause a large fraction of any frequency guideline.
3. No quantitative guideline is proposed for the fourth strategy, the LERF guideline is used as a surrogate.
4. For rare initiators, emphasis is placed on Strategy 1, limit initiator frequency.
5. Measures to mitigate late large releases are also appropriate. A conditional probability of a late large release (up to 24 hours after the onset of core damage) of $\leq 10^{-1}$ is proposed.

Two methods of quantitatively assessing the level of protection against accidents at a given nuclear power plant are also depicted in Figure 3-1:

- a prevention-mitigation assessment considers the strategies in pairs,
- an initiator-defense assessment considers the strategies individually.

The quantitative guidelines are discussed in the context of these two assessment methods in the following sections. In this context, mean risk measures quantified in full-scope, plant-specific PRAs would ideally be compared to the quantitative guidelines. Full scope PRAs address internal and external initiating events as well as accidents initiated in all operating modes. The frequencies in Figure 3-1 are, accordingly, stated per calender year rather than per year of reactor operation. Other relevant considerations regarding the terms core damage frequency (CDF), large early release frequency (LERF), and large late release are discussed in Section 3.4. Practical considerations regarding the application of the quantitative guidelines to the Option 3 study in the presence of uncertainties and plant-to-plant variations is provided in Section 4.

3.1 Prevention-Mitigation Assessment, Consider the Four Strategies in Pairs

As indicated in Figure 3-1, a prevention-mitigation assessment examines the effectiveness of the strategies in pairs.

To assess the effectiveness of the two preventive strategies, a plant's mean CDF is compared to the quantitative guideline of 10^{-4} per year. If the CDF is 10^{-4} per year or less the latent-cancer QHO is generally met.

To assess the effectiveness of the two mitigative strategies the conditional probability of a large early release given a core damage accident is compared to the guideline of 10^{-1}. (The term large early release is explained in Section 3.4.) The LERF is the product of CDF and the conditional probability of a large early release given core damage. Therefore, if the CDF and conditional probability of large early release guidelines are both met, LERF will be 10^{-5} per year or less. Based on Level 3 PRA results, the early-fatality QHO is generally met if LERF is 10^{-5} per year or less.

The use of a LERF guideline developed from the early-fatality QHO, does not imply that risks associated with late containment failures can or will be ignored. Measures to remove heat from containment and to reduce the concentrations of radionuclides that could otherwise result in later large releases are also appropriate to provide defense against situations in which evacuation is precluded or rendered ineffective, to protect plant workers, and to help ensure plant radiological conditions allow implementation of severe accident management guidelines. The LERF guideline does not adequately address this situation and thus an additional guideline applicable out to approximately 24 hours is proposed to assess the performance of containment and containment engineered safety features. Specifically, a guideline of 10^{-1} or less is applied to the conditional probability of a large late release (i.e., one that does not contribute to LERF, but occurs within approximately 24 hours of the onset of core damage). The potential for late large releases is discussed further in Section 3.4.

Based on existing PRAs the proposed quantitative guidelines provide a reasonable balance between the preventive and mitigative strategies. Uncertainties tend to grow as postulated accidents proceed in time, and existing containments were not designed for severe accidents, A more stringent guideline for the conditional probability of a large early release given a core damage accident could, therefore, be impractical for many plants. On the other hand setting the guideline for CDF at 10^{-4} per year emphasizes the preventive strategies where PRA results are most plentiful and accurate.

3.2 Initiator-Defense Assessment, Consider the Four Strategies Individually

In an initiator-defense assessment events that could conceivably initiate a core damage accident are divided into three categories: anticipated, infrequent, and rare. For each initiator category a quantitative guideline is established for each of the four defense-in-depth strategies. Accident sequences postulated during low power should be weighted according to the anticipated duration of the shutdown period. For example, an accident that can only happen during one week every two years but which has an occurrence probability of 10^{-4} during that week has a frequency of $(10^{-4}/\text{week})*(1\ \text{week}/2\ \text{years}) = 5\text{x}10^{-5}/\text{year}$.

In PRAs, accidents are binned (grouped) by their initiators. Accidents that cause similar behavior and require functionally identical responses to avoid core damage or containment failure are binned together. For example, loss-of-coolant accidents (LOCAs) are often classified as small, intermediate, or large depending on the systems required to respond. Some accidents types (e.g., anticipated transients without scram [ATWS] and station blackout [SBO]) reflect functionally similar sequences of events. For Option 3, three groups of initiator are defined as frequent, infrequent, and rare initiator categories. Each of these are described below.

Anticipated initiators are either expected to occur or may well occur during the life of an individual plant. Examples include inadvertent opening of a steam generator relief or safety valve, steam pressure regulator malfunction, reactor coolant pump trip, and loss of offsite power. The term anticipated operational occurrence (AOO), as used in safety analysis reports, describes a sequence of events started by an anticipated initiator and compounded by one or more single active failures. Plants are generally designed to withstand anticipated operational occurrences with no reactor coolant system or containment damage.

The frequency of a significant group (bin) of anticipated initiators is typically greater than 10^{-2} per year. Anticipated initiators may be risk-significant if multiple failures of responding systems and components lead to core damage. Since the 1979 accident at TMI-2, industry efforts to reduce the frequency of anticipated initiators have been quite successful. Licensees are motivated to reduce the frequency of anticipated initiators by economic as well as safety considerations, and their performance is easily monitored. Therefore, no quantitative guideline for the frequency of anticipated initiators is required to risk-inform existing regulatory requirements. Figure 3-1 simply indicates that the frequency of such initiators is typically on the order of one per year.

The quantitative guideline proposed for the probability of core damage conditional on the occurrence of an anticipated initiator is 10^{-4}. This is consistent with previous Commission Guidance which approved the use of a 10^{-4} CDF objective.

A quantitative guideline of 10^{-1} or less is set for the conditional probability of a large early release given an anticipated initiator that leads to core damage. A quantitative guideline of 10^{-1} or less is also set for the conditional probability of a large late release (i.e., one that does not contribute to LERF, but occurs within approximately 24 hours of the onset of core damage). These are the same guidelines used in the prevention-mitigation assessment. Under the proposed defense-in-depth approach, the fact that core damage results from an anticipated initiator is irrelevant to the level of containment performance desired given core damage. The combination of 10^{-4} CDF and 10^{-1} for conditional probability of a large early release will help ensure the LERF objective of 10^{-5}/ry.

A quantitative guideline has not been set for the fourth line of defense, that is, for the probability of acute fatality given a large early release. This risk measure has not been explicitly considered in past studies, but NUREG-1150 and other Level 3 risk assessments demonstrate that the QHOs are generally met if the quantitative guidelines for the first three strategies are met. In part, this is because wind and rain patterns generally assist in limiting the fraction of the population exposed to offsite radionuclide releases. Offsite protective actions are, nevertheless, an essential element of the risk-informed defense-in-depth approach.

Infrequent initiators are not expected to occur over the life of any single plant but may, nevertheless, occur in the population of plants and could be risk significant. The frequency of a significant group (bin) of infrequent initiators is typically less than 10^{-3} per year. Existing plants were designed to withstand many infrequent initiators including pipe breaks in nuclear steam supply systems (NSSSs) and safe-shutdown earthquakes.

The quantitative guideline is less than10^{-2}/ry for the frequency of all initiators in the infrequent category. On an industry-wide basis it is possible to monitor performance against this quantitative guideline. The quantitative guideline for the conditional probability of core damage given an infrequent initiator is 10^{-2} to ensure a CDF less than 10^{-4}. Based on existing PRAs the proposed quantitative guidelines provide a reasonable balance between initiator prevention and core damage prevention. The guidelines for the two mitigative strategies are again a conditional probability of a large early release of 10^{-1} or less and a conditional probability of a large late release of 10^{-1} or less.

For accidents in which one or more of the four high-level defense-in-depth strategies is precluded, the individual strategy guidelines may be less important than their products; that is, more emphasis needs to be placed on the strategies that remain. For example, consider a PWR interfacing-system loss-of-coolant accident (ISLOCA) in which containment is bypassed. The early containment failure probability is 1.0, therefore the quantitative guideline of 10^{-1} cannot be achieved. Since no special ECCS is provided for ISLOCAs, there is a need to limit the relative frequency of such LOCAs and consider them in emergency planning.

Rare initiators are those excluded from the anticipated and infrequent categories because they are extremely unlikely. Examples of rare initiators include aircraft impact, meteor strikes, and very large earthquakes. As a quantitative guideline, the total frequency of all rare initiators should be 10^{-5} per year or less. Although some rare initiators could fail containment or preclude emergency response, this is not true for all rare initiators, and existing Level 3 PRAs indicate the rare initiator frequency goal of 10^{-5}/yr should not cause the QHOs to be exceeded.

There should be a high level of confidence that the collective frequency of all rare initiatiors is less than 10^{-5} per year. The complete set of rare events cannot be delineated with certainty, and uncertainties in the frequencies of rare events are generally large. Initiators of a specific type (bin) should, therefore, be classified as infrequent only if their frequency is demonstrably less than 10^{-6} per year. Current regulatory guidance imposes even more stingent frequency criteria in screening for external initiators to be addressed in safety analysis reports (Ref. SRP 2.3.3).

The risk-informed defense-in-depth approach does not ignore rare events. Tactics such as research, inspection, testing, and monitoring are applied to validate the low frequencies of rare initiators. Generally, however, a risk-informed regulation will not require plant structures, systems, and components be specifically designed to cope with rare initiators. Existing plant features provide some degree of protection against core damage and radionuclide releases for many rare initiators, and risks posed by rare initiators should certainly be addressed in PRAs. However, to focus on reducing risks associated with rare initiators would draw attention away from, and potentially increase risks associated with, more likely initiators.

3.3 Additional Thoughts on Quantitative Guidelines

When the first two strategies, prevent initiators and prevent core damage, are considered as a pair, the relevant quantitative guideline is a CDF less than 10^{-4} per year. When these strategies are considered individually, the products of the quantitative guidelines for the two strategies is the 10^{-4} per year CDF quantitative guideline. That is, meeting the risk-informed regulations should be consistent with achieving a CDF of less than 10^{-4} per year. To meet such a guideline, the regulations should assure a higher response reliability (perhaps more redundancy and diversity) for more frequent initiators.

A different approach has been taken for rare events. Some of these events, should they occur, have the potential to progress directly to offsite releases of radionuclides. Because the core damage prevention and containment strategies may be unavailable for rare initiators, the frequency quantitative guideline for rare initiators is set more stringently than 10^{-4} per year. Specifically, the quantitative guideline is less than 10^{-5} rare initiators per year with no single type of rare initiator being allowed to account for the entire guideline.

The fourth high-level defense-in-depth strategy involves emergency planning and response, which are essential for protecting the public health and safety. Although a quantitative guideline has not been set for this strategy, credit has been taken for its effectiveness in establishing subsidiary quantitative guidelines compatible with the QHOs for the first three strategies. As noted earlier, pre-planned protective actions may be particularly important for accident scenarios in which one or more of the first three strategies are compromised. For example, for an ISLOCA, which bypasses containment, an early containment failure guideline cannot be used; therefore, the fourth strategy becomes necessary.

The product of the quantitative guidelines for the two strategies in method (1) and the three strategies for each of the three initiator types in method (2) is a LERF of $<10^{-5}$ per year. As stated earlier, this generally assures that the early fatality QHO of #$5\text{x}10^{-7}$ per year will be met. Setting the individual strategy quantitative guidelines to yield a lower aggregate value would be unnecessarily conservative.

3.4 Core Damage and Large Release

Many of the risk measures and quantitative guidelines in Figure 3-1 are frequencies or conditional probabilities of core damage or large early release. It is, therefore, appropriate to consider these terms further.

To be risk significant, core damage must involve the release of fission products from the fuel. A risk-significant level of core damage exceeds that specified in the ECCS acceptance criteria of 10 CFR 50.46. The ECCS acceptance criteria permit only one percent of the cladding to be oxidized. Only a fuel-clad gap release would occur given this level of damage. The purpose of the ECCS acceptance criteria is, however, not to establish a risk-significant level of core damage but to set a level of core damage appropriate for a design basis accident.

A typical PRA criteria for core damage requires the water level to be below a certain level with no imminent restoration of coolant to the core region so a melt release of fission products from the fuel is assured. This corresponds roughly to the point where computer analyses become complicated by geometry changes associated with melting and relocation of core materials.

In Regulatory Guide 1.174, LERF is described as the frequency of those accidents leading to significant, unmitigated releases from containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure at or shortly after vessel breach, containment bypass events, and loss of containment isolation. This definition is consistent with accident analyses used in the safety goal screening criteria discussed in the Commission's regulatory analysis guidelines.

Not every containment bypass or early failure would result in a large release. To be risk-significant containment leakage must far exceed the design basis containment leak rate. Containment failure modes that result in scrubbed releases or leak paths that are isolated before the onset of significant core damage generally do not lead to large releases. However, it needs to be recognized that the determination of what constitutes a scrubbed release is dependent upon several factors, including the depth of the water pool and pool temperature.

In many postulated severe accidents, reactor vessel bottom head failure occurs before effective evacuation. Substantial containment loads accompany bottom head failure. Large releases, therefore, tend to be most likely before or shortly after vessel bottom head failure. Containment failure resulting in a large early release is less likely for degraded-core accidents in which core degradation is arrested in time to prevent vessel bottom head failure.

For some plants, large releases could occur hours after reactor vessel bottom head failure. An example would be a release due to containment overpressurization or high temperature while core-concrete interactions are proceeding in the absence of an overlying water pool. Containment heat removal systems may be inoperable in this scenario, and natural processes would take hours after the completion of core-concrete interactions to remove radionuclides from the containment atmosphere.

Effective evacuation can mitigate the threat of acute health effects offsite given such a delayed large release. However, there are accidents in which external events may preclude or hinder evacuation efforts. Plant workers would also need to be protected from any delayed large release. As indicated in Section 3.1, a quantitative guideline has also been included to reflect the need for defense-in-depth against the threats posed by such delayed releases. Specifically, the conditional probability of a large late release should be 10^{-1} or less. Late in this context extends to approximately 24 hours after the onset of core damage. This period is generally sufficient to provide for significant reduction of airborne radionuclide concentrations in containment. The use of a 24-hour time period forces the staff to review the effectiveness of containment and containment engineered safety features beyond vessel breach. It also represents a reasonable delay for interventions (e.g., controlled elevated containment venting) to cope with long-term or gradual energy releases to containment.

4.0 TREATMENT OF UNCERTAINTIES

In making risk-informed changes to the existing regulatory requirements it is important to consider the treatment of uncertainties from two perspectives: (1) assessing the impact of contemplated changes relative to the quantitative guidelines and (2) developing risk-informed options to existing requirements that reduce the potential impact of uncertainties on the decisionmaking process. Both perspectives are discussed in this section.

4.1 Developing Risk-Informed Alternative

To the extent possible, a risk-informed alternative to existing technical requirements of a regulation will be delineated in such a way that the impact of uncertainties on the decisionmaking process is accounted for.

Regulatory requirements impacting the design of existing plants were, for the most part, promulgated before PRA was broadly applied. Yet, it is fair to say that a driving intent of existing regulations is to define the design envelope of plants such that events within the design envelope are not significant contributors to risk. PRAs and IPEs tend to confirm that this intent has been realized; that is, risk-dominant accident scenarios are generally those involving initiators or multiple failures not postulated in the design of existing plants.

Risk-informed regulations will continue to assure that events within the design envelope are not significant contributors to risk. For example, for routine operation, including anticipated operational occurrences, requirements necessary to minimize cladding failures will be retained, and risk significant levels of core damage will not be accepted for design basis accidents.

In considering a change to an existing regulatory requirement it is important to estimate the overall impact on risk measures of the actual plant changes (to SSCs, inspections, testing, operating procedures, training, emergency plans, etc.) that would ensue. An overall assessment is required to preclude unintended repercussions. For example, if it were demonstrated that very large pipe breaks could be excluded from consideration under the Emergency Core Cooling Systems (ECCS) acceptance criteria of 10 CFR 50.46, such breaks might still represent reasonable design-basis events for containment to account for uncertainties.

The alternative promulgated may be impacted by the type of uncertainty that exists. Although the quality and coverage of risk assessments continues to evolve, completeness uncertainty can never fully be eliminated. Completeness uncertainty associated with the scope of a reference PRA should be addressed by applying risk insights from other relevant PRAs. Completeness uncertainty associated with what has not been thought of or cannot currently be modeled is a principal reason for adopting the high-level defense-in-depth approach and strategies described in Sections 2.2 and 2.3.

Safety margin is often appropriate to compensate for model uncertainty regarding the loads and capacities, for example, to keep passive failures of mechanical components from dominating the failure rates of responding systems. The use of safety margin is discussed further in the next subsection

4.2 Safety Margin

The treatment of uncertainty from the design basis perspective involves the notion of safety margin. Colloquially, terms like safety margin and safety factor imply a measure of the conservatism employed in a design or process to assure a high degree of confidence that it will work to perform a needed function.

There are, in the literature, many different definitions of safety margin. Some are probabilistic. Others are deterministic. For example, safety margin is sometimes defined as the ratio of the ultimate failure stress to the design stress. In delineating risk-informed options to existing regulatory requirements, probabilistic considerations will be applied to the extent possible. The following is typical of a probabilistic definition (Ref. 13): safety margin is the probability (or level of confidence) that a design or process will perform an intended function.

To illustrate the significance of a probabilistic approach, consider the common question: Will the capacity of a structure, system, or component (SSC) be exceeded during an accident? If there is no uncertainty in the imposed stress and no uncertainty in the capacity of the SSC, there is no uncertainty in the answer. Assume a known stress is only slightly less than a known capacity. Replacing the SSC with one that is twice as strong would be useless because the failure probability would still be zero.

Generally, of course, there is uncertainty in the imposed stress, the capacity, or both, and the greater the uncertainties, the greater the need for safety margin. Safety margin may indicate the probability that an uncertain stress exceeds a known capacity or the probability that a known stress exceeds an uncertain capacity. Often there is uncertainty in both the stress imposed and the capacity. In some of these cases, the overlap of the stress and performance distributions can be quantified. More frequently, in formulating regulatory requirements, acceptance criteria or failure criteria are delineated to, in effect, fix the capacity so that safety margin can be stated as the probability of exceeding the acceptance criteria. For example, compliance with the ECCS acceptance criteria of 10 CFR 50.46 can be demonstrated using best-estimate codes provided that "uncertainty is accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria, there is a high level of probability that the criteria would not be exceeded."

The working definition of safety margin does not preclude the use of conservative or bounding calculations to demonstrate acceptable safety margin. For example, ECCS calculations based on 10 CFR 50 Appendix K, provide a conservative alternative to best-estimate calculations with uncertainty propagation. However, consistent with the intent to use probabilistic considerations where possible, safety margin could be applied to assure a component's structural failure probability is comparable to the probabilities of other failure modes. There is little to be gained by requiring more capacity as long as the structural failure cannot cause other failure events.

Excessive safety margins benefit neither the NRC nor the nuclear industry. Excessively conservative requirements can, in fact, lead to incorrect safety conclusions and regulatory decisions, that may actually reduce plant safety by masking issues of higher safety significance. Mandated excessive conservatism can also produce artificial regulatory concerns.

What constitutes adequate margin and what constitutes excess margin? The answer to this question will always involve engineering judgement. Preliminary guidance for the Option 3 study is offered below, but it is anticipated that guidance regarding safety margin will evolve as the study progresses.

Safety margin is imposed to account for uncertainties in data and models by conservatisms placed in acceptance criteria and methods for demonstrating compliance with acceptance criteria. The approach preferred for the Option 3 study is (1) to specify reasonable safety margin in acceptance criteria based on probabilistic considerations and risk insights, and (2) to use best-estimate code calculations with uncertainty propagation to demonstrate compliance based on a computed 95th percentile. When this approach is precluded, an attempt will be made to achieve an equivalent level of safety margin in order to avoid excessive conservatism.

4.3 Types of Uncertainty

Aleatory uncertainty is that addressed when the events or phenomenon being modeled are characterized as occurring in a "random" or "stochastic" manner, and probabilistic models are adopted to describe their occurrences. This aspect of uncertainty gives PRA the probabilistic part of its name.

Epistemic or state-of-knowledge uncertainty is that associated with the analyst's confidence in the predictions of the PRA model. It reflects the analyst's assessment of how well the PRA model represents the actual system being modeled. As such, it generally varies from analyst to analyst.

Aleatory uncertainty is built into the structure the PRA model. Uncertainty in the results obtained from the PRA model is epistemic. Epistemic (state-of-knowledge) uncertainties are commonly divided into three classes: parameter uncertainty, model uncertainty, and completeness uncertainty.

Parameter uncertainties are those associated with the values of parameters of the PRA models. They are typically characterized by establishing probability distributions on the parameter values. These distributions can be interpreted as expressing the analyst's degree of belief in the values these parameters could take, based on his state of knowledge and conditional on the underlying model being correct. It is reasonably straightforward to propagate the distribution representing uncertainty on the basic parameter values to obtain probability distributions on Level 1 PRA results such as core damage frequency and accident sequence frequencies. Uncertainty characterization is much more difficult in Level 2 PRAs, and generally impractical in Level 3 PRAs.

Model uncertainties are those associated with incomplete knowledge regarding how models used in PRAs should be formulated. Such uncertainties arise, for example, in modeling human performance; common cause failures; and mechanistic failures of structures, systems and components; and large-early releases. Model uncertainties grow in number and magnitude as one proceeds from Level 1 to Level 2 and 3 PRAs.

In some cases, where well-formulated alternative models exist, PRAs have addressed model uncertainty by using discrete distributions over the alternative models, with the probability (or weight) associated with a specific model representing the analyst's degree of belief that the model is the most appropriate. For example, different hypotheses lead to different seismic hazard curves. Discrete weights summing to one are assigned to these curves. Another approach to addressing model uncertainty is to adjust the results of a single model through the use of an adjustment factor. Using such approaches, model uncertainty can be propagated through the analysis in the same way as parameter uncertainty.

More typically, however, 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, although the uncertainties are recognized, they are not quantified. Assumptions are made and specific models are adopted. Unquantified model uncertainty also arises because PRAs bin the continuum of possible plant states in a discrete way. Such approximations introduce biases (model uncertainties) into the results.

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

Completeness uncertainty refers to things that are not modeled in a PRA. This includes risk contributors that can be modeled but are often excluded such as external events and accidents at low power and shutdown. It also includes considerations for which methods of analysis have not been developed, for example, operator errors of commission, heroic acts, and influences of organizational performance cannot now be explicitly assessed. Finally, it includes initiators and accident scenarios that have not been conceived.

Incompleteness in a PRA can be addressed for those scope items for which methods are in principal available, and therefore some understanding of the contribution to risk exists. This may be accomplished, by supplementing the 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. Defense-in-depth is used to compensate for other completeness issues.

4.4 Risk Impacts of Changes

The appropriate numerical measures to use in comparing PRA results to the quantitative guidelines in Figure 3-1 are mean values. The mean values referred to are those that result from the propagation of distributions assigned to uncertain input parameters (and occasionally to alternative models). Methods for propagating input parameter distributions have been developed and, except for dispersion and health effects models, were applied in the NUREG-1150 risk assessments. The resulting uncertainties are large, exceeding two orders of magnitude from the 5-th to 95-th percentile on core damage frequency. The spread in CDF results from the IPEs is generally consistent with the NUREG-1150 uncertainty estimates. As previously mentioned, uncertainties pertaining to phenomenological models tend to increase as accident scenarios progress. In many cases, this leads to significant uncertainties in containment failure probabilities. As part of the NUREG-1150 effort, formal expert elicitation methods were used to quantify key phenomenological uncertainties. Except where significant subsequent research has been conducted, the NUREG-1150 results generally provide the best available quantifications of such uncertainties.

Guidance regarding the treatment of uncertainties will evolve as the Option 3 study progresses; current perspective is provided below by considering a series of questions:

4.4.1 How Risk-Significant Will the Changes Be?

For each affected class of nuclear power plants, the impact of a contemplated regulatory change will be examined relative to the quantitative guidelines in Figure 3-1. The impacts on CDF and LERF are good indicators of impacts on latent-cancer and acute-fatality risks, respectively. Conceptually, averaged over all plants in a class, three possible outcomes can be envisioned for each risk measure. The measure may decrease relative to its quantitative guideline, the impact on the guideline may be indeterminant, or the measure may increase relative to its quantitative guideline.

It is envisioned that most changes would have a major impact on only one of the strategy columns of Figure 3-1. It is unlikely, but conceivable, that a proposed change could result in mixed impacts, for example, decrease CDF while increasing LERF or vice versa. In such cases, for the discussion that follows, the impact on risk is taken to be that on CDF. This is because change in CDF is used to classify risk decreases in the Regulatory Analysis Guidelines and risk increases in Regulatory Guide 1.174. The change in CDF is also a good indicator of societal costs associated with a change.

Risk Decreases

Qualitative arguments may suffice to demonstrate risk would decrease for a particular class of plants as a result of a proposed risk-informed regulatory change.

Changes that would decrease risk, but impose additional licensee burden will be included in risk-informed alternative regulations without detailed value impact analysis because compliance with the alternative regulation is voluntary; that is, licensees may, if they choose, continue to comply with the existing regulation. However, the reasonableness of the additional burden versus the risk decrease will be considered.

There is little point in developing an alternative that no licensee will choose. If the magnitude of the decrease in CDF passes the safety goal screening criteria of the Regulatory Analysis Guidelines, and the change has the potential to pass a value impact analysis, it will be referred to the Generic Safety Issues program for potential mandatory implementation. In particular, changes that would decrease core damage frequencies by greater than 10^{-5} per year while reducing licensee burdens would be referred.

Considerations of uncertainty regarding risk decreases in the Option 3 study must be sufficient to demonstrate that nothing has been overlooked that would actually result in a risk increase.

Risk Impact Indeterminate

Generally if it cannot be determined whether a contemplated change to an existing regulatory requirement would result in a risk increase or a risk decrease, the change would not be risk-informed. But, if it can be demonstrated that the absolute magnitude of the impact would be very small (less than 0.1% of any quantitative guideline) and licensee burden reduction would exceed the dollar value of a 0.1% increase, the option may be included as part of a risk-informed alternative regulation.

Risk Increases

As stated in Section 3, the quantitative guidelines in Figure 3-1 reflect a desired level of safety against which industry averaged risk measures can be compared; a level that is "safe enough" based on the Safety Goal Policy Statement while providing reasonable balance among the defense-in-depth strategies. Changes to existing regulatory requirements should not, therefore, lead to risk increases that go beyond the level of safety implied by the quantitative guidelines.

In principle, if each plant had a high-quality, full-scope, Level 2 PRA with quantitative treatment of uncertainties, the industry-wide impact of alternatives offered under Option 3 could be tracked. In this case, the risk increase (if any) associated with the next alternative could be set relative to the current industry-wide risk profile. This is not a realistic possibility, at least not in the time frame of the initial Option 3 efforts.

Uncertainties must be assessed in making a determination that increases in core damage and large-early-release risk measures would be ~10% or less of the quantitative guidelines. It is anticipated that results from existing PRAs and IPEs coupled with bounding analyses will suffice for this purpose for many cases. Licensee analyses per RG 1.174 may provide a good starting point for assessment of industry-wide risk impacts of some small changes.

As a general principle, changes to existing regulations that would result in risk increases will be avoided if the magnitude of the risk increase is difficult to quantify and little associated NRC or licensee burden reduction would accrue. Where there is potential for burden reduction, that potential should be substantial enough to justify the magnitude of the risk increase.

4.4.2 How Will Initiating Events be Classified (Infrequent versus Rare)?

In assessing whether a particular type of initiating event should be considered rare consideration will be given to the design-basis initiating events postulated in licensee's safety analysis report and other initiating events, both internal and external, identified in PRAs.

Where possible, probabilistic models of initiating event frequencies, using data based on observed occurrence rates to the extent possible, will be utilized.

Models of initiating event frequencies and the parameters of these models will be analyzed to assure that the mean frequency of occurrence of all internal and external initiating events classified as rare does not exceed the 10^{-5} per year guideline. With a high level of confidence, the uncertainty associated with any single parameter or other plausible model choice should not cause this guideline to be exceeded.

It should be noted that the 10^{-5} per year guideline for the collective frequency of rare initiating events includes both internal and external initiating events.

If, based on the preceding considerations, modifying an existing design-basis initiator is contemplated, the potential impact of the change on plant risk measures would, of course, have to be assessed as described in the preceding subsections. For example, it has been argued that very large pipe breaks should be excluded from consideration under the ECCS acceptance criteria of 10 CFR 50.46 because data and fracture-mechanics analyses indicate their frequency of occurrence is very low. Before making such a change to an existing regulatory requirement, the risk impact of plant changes that might result would have to be assessed.

5.0 IMPLEMENTATION OF FRAMEWORK

As stated in the introduction, the framework will be used to guide efforts to develop risk-informed changes to the technical requirements of the regulations in 10 CFR 50. Through implementation of the framework, it is anticipated that Phase 1 of the Option 3 study will identify existing requirements that:

- will be retained
- can be eliminated
- will be revised, enhanced or replaced

In implementing the framework (with its quantitative guidelines), three major steps are followed as depicted in Figure 5-1. The process begins with the selection and prioritization of the regulations in 10 CFR 50 to be risk-informed as discussed in Section 5.1. After a regulation is selected and its technical bases are studied, a risk-informed alternative to the technical requirements of that regulation will be developed as discussed in Section 5.2. In the third step, which is discussed in Section 5.3, an evaluation is performed of the risk-informed alternative.

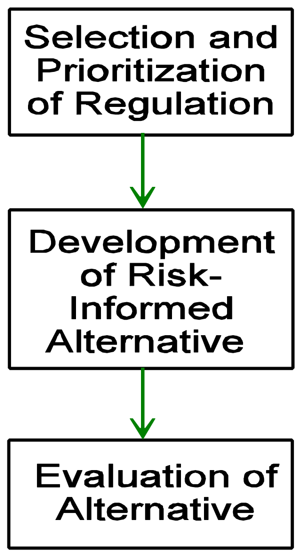

Figure 5-1 Approach for selection, development, and evaluation of risk-informed alternative.

5.1 Step 1: Select and Prioritize Regulations to be Risk Informed

The first major element in the process is the selection of the regulation that needs to be risk-informed. The selection and prioritization process consists of five major components as shown in Figure 5-2: a coarse screening of the regulations in 10 CFR Part 50, a safety concern screening to identify "holes" in the regulations, a second screening to determine if a regulation even warrants risk-informed change, a linking to identify ties to other regulations or implementing documents, and a prioritizing of the regulations to be risk-informed.

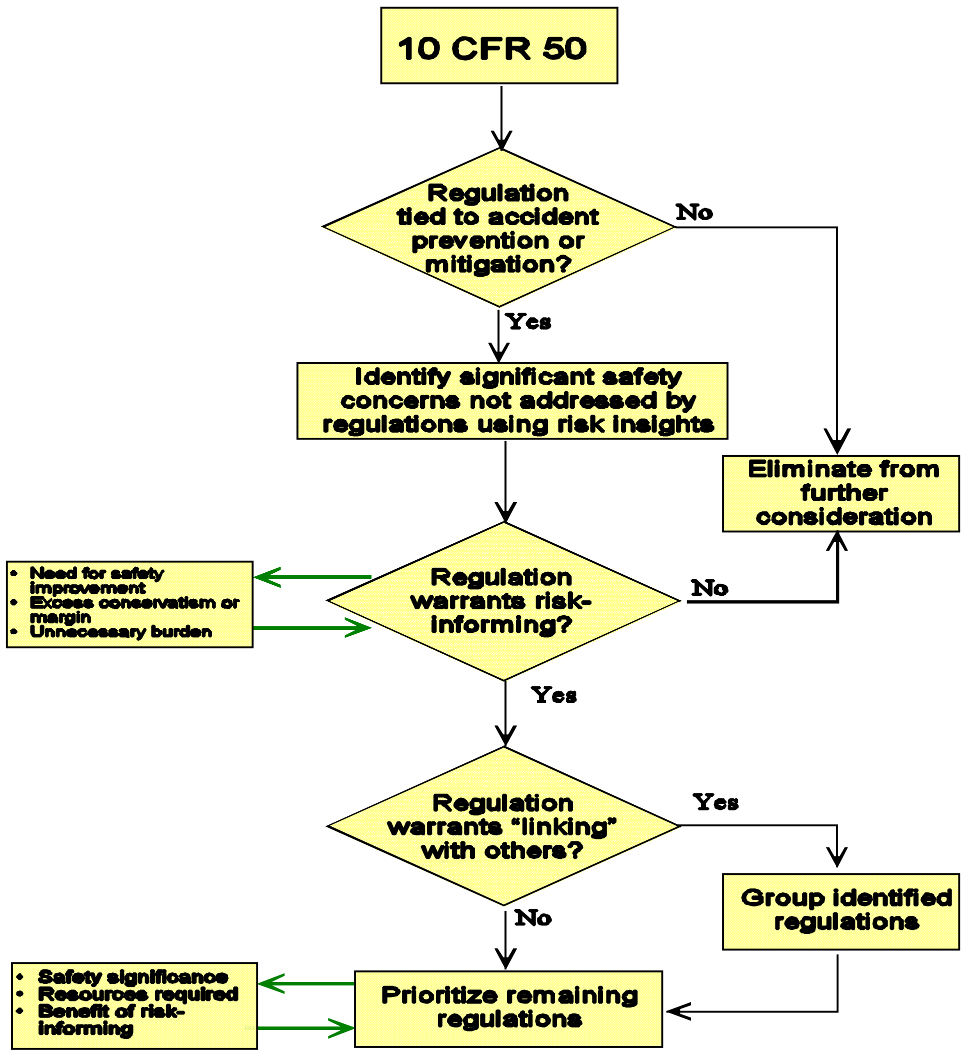

Figure 5-2 Process for selecting and prioritizing regulations to be risk-informed.

Coarse Screening of 10 CFR 50

As indicated previously, this framework is directed toward existing regulations that have an impact on prevention or mitigation of core-damage accidents, because these accidents present the most risk to the public and risk information is most prevalent for such accidents. In the future, the framework can be adapted and extended to apply to regulatory requirements that impact non-core-damage accidents.

A preliminary coarse screening was conducted of Parts 50 and 100, and each regulation was placed in one of two bins:

1. Regulations that do not have an impact on prevention or mitigation of core-damage accidents. These consist of sections that are purely procedural or provide legal or technical definitions, refer to enforcement provisions and/or penalties for misconduct, concern financial and insurance requirements, specify routine exposure limits from plant operation, pertain to decommissioning, or impact only non-core-damage accidents.

2. Regulations that could potentially impact prevention or mitigation of core-damage accidents.

The results of the preliminary screening are presented in Appendix A. Many of the regulations falling into Bin 1 are process-oriented. Although not themselves candidates for risk-informed changes, it is conceivable that some process-oriented regulations may have to be changed for the sake of consistency due to risk-informed changes made to regulations in Bin 2. Bin 2 includes all of the possible candidates to be risk informed identified in a recent Nuclear Energy Institute (NEI) letter. The prime candidates identified by NEI for risk-informed assessment and change are (Ref. 14):

- LOCA, ECCS analyses, 10 CFR 50.46 and Appendix K to Part 50
- Codes and Standards, 10 CFR 50.55a
- GDC 4, Appendix A to Part 50 and associated regulatory guidance documents that are linked to pipe-whip and dynamic effects
- Environmental qualification of electric equipment important to safety for nuclear power plants, 10 CFR 50.49
- Standards for combustible gas control system in light-water-cooled power reactors, 10 CFR 50.44
- GDC 19, Appendix A to Part 50 and associated regulatory guidance documents linked to control room ventilation
- GDC 17, Appendix A to Part 50 and associated guidance documents related to electrical power systems

Safety Concerns Not Addressed in 10 CFR 50

In the process of making risk-informed changes to the existing regulations, it is also important to identify risk-significant safety issues not explicitly addressed in current regulations. At a very coarse level, an attempt has been made to find issues that are important to accident risks, in terms of accident types, which are not addressed in the current Part 50 regulations. Table 5-1 shows a mapping of accident types that are important to CDF or LERF to Part 50 regulations. Further investigation is necessary in order to identify whether there are major risk contributors associated with these accident types that need to be addressed by the regulations.

Table 5-1 Regulatory Coverage of Some Accidents Important to Risk (Preliminary)

Accident Types Important to CDF/LERF	Regulations in Part 50
SBO	50.63, 50.34 (f) (ix)
ATWS	50.62
LOCAs	50.34 (f) (iv) - Small Break LOCA, 50.46 - ECCS Acceptance Criteria, App. K, App. J
Transients with DHR Loss	50.34 (f) (i) - DHR Reliability
Transients with Injection Loss	50.34 (f) (v), 50.34 (f) (vii), 50.34 (f) (viii), 50.34 (f) (x), 50.34 (f) (xi)

Table 5-1 Regulatory Coverage of Some Accidents Important to Risk (Preliminary)

Accident Types Important to CDF/LERF	Regulations in Part 50
Early Containment Failure	50.34 (f) (xii), 50.44 - H2 control, App. A
Containment Bypass-ISLOCA/SGTR	App. A (very indirectly)
Loss of Containment Isolation	App. A
Internal Fire	App. R
Internal Flood	
External Events	(Part 100 for siting), App. S
Events at Low Power and Shutdown	

One feature that is immediately obvious from the table is the fact that many of the risk-significant accident types are only covered by 50.34 (f) (..), the "TMI-related regulations." This set of regulations applies only to plants whose license applications were pending as of February 1982. (The paragraph under 50.34 (f) identifies a specific set of plants to which these rules were applicable; none of these plants have been constructed.) By inference, these regulations do not apply to the current set of operating plants, so there is, in principle, the possibility that one or more risk-significant safety issues may need to be assessed in the risk-informed process.

Some risk-significant accident types and related events do not find any mention in the current regulations. Except for hydrogen, threats posed by severe accidents are not specifically mentioned in existing regulations. Often, one has to "stretch" the rather general language contained in the regulation to infer its applicability to a particular accident class. An example would be interpreting the contents of Appendix A to cover the containment bypass accident category.

Second Screening

As indicated in Figure 5-2, a second screening is performed to identify those regulations that do not warrant risk-informed changes and can be eliminated from further consideration because (1) there is no need for safety improvement, (2) there is no excess conservatism or margin in the regulation's technical requirements, and (3) there is no unnecessary burden associated with the the technical requirements of the regulation.

Any regulation for which a safety enhancement may be necessary, based on the quantitative guidelines presented in Figure 3-1, will clearly need to be retained and prioritized for risk-informed changes. For those regulations for which no safety enhancement is deemed necessary for its technical requirements, given that licensees will have the option of choosing between an existing regulation and its risk-informed counterpart, there is little purpose in promulgating a risk-informed regulation that does not offer a significant tangible benefit to at least some licensees. Accordingly, only those regulations whose technical requirements (of this latter category) which result in unnecessary burden reduction will be retained and prioritized for risk-informed changes.

Linking

Further evaluation of the remaining regulations is performed to identify any ties, overlaps or redundancies to determine if sets of existing regulations should be "linked or grouped" for further risk-informed study. There are instances in the current 10 CFR 50 where a particular aspect of plant design, construction or operation is addressed in more than one regulation or associated implementing document. In these instances, it may be more efficient and effective to address all of the impacted regulations together as a single group. In particular, linking regulations will help to avoid (or at least be cognizant of) situations where a particular technical requirement may be modified or eliminated in a risk-informed regulation, but that same technical requirement is still specified, as it currently exists, in another regulation (or associated implementing document). In the discussion that follows the singular use of the term regulation should be understood to apply to such linked sets of regulations.

Prioritization

The regulations that survive the secondary screening are prioritized. The highest priority candidates are selected for detailed evaluation in Step 2. Three factors are considered in prioritizing candidate regulations to be risk informed:

- the safety significance of each regulation,
- the potential resources required to risk inform (considering complexity, information requirements, need for a demonstration plant, time, manpower, etc.), and
- the benefit of making risk-informed changes to the regulation (e.g., the potential for reducing unnecessary burden).

In assessing safety significance, both the impact of a regulation on the quantitative guidelines in Figure 3-1 and the number of plants affected by the regulation will be considered. It is generally straightforward to determine which, if any, of the four high-level defense-in-depth strategies a regulation impacts. The safety significance of the impact can, in some cases, be characterized qualitatively. In other cases simple quantitative analyses of the contributions from accident scenarios impacted by the regulation may be performed based on available IPEs and PRAs.

5.2 Step 2: Development of Risk-Informed Changes

The second major element in the process is to develop the risk-informed changes to the technical requirements for the high-priority regulations identified in Step 1. Two approaches are followed for developing risk-informed changes to a regulation. Both approaches begin with an examination of the concern or concerns that necessitated the regulation, and both approaches have the same overall objective, which is to develop risk-informed requirements for dealing with the identified concern.

One approach starts from the current set of technical requirements of the regulation and attempts to develop risk-informed changes by analyzing the technical requirements. The second approach takes a fresh start by applying the four high-level defense-in-depth strategies; in effect, ignoring the existing technical requirements of regulation.

There are two principal reasons for following two approaches to developing a risk-informed alternative to a regulation. The first reason is for completeness. Following both of the above approaches gives greater confidence that all reasonable risk-informed options have been identified. The second reason is to identify a risk-informed alternative that is the most optimal by looking at the concern from an alternative perspective, that is, without being constrained, or unduly influenced, by the existing requirements.

Potential changes identified by either of these two approaches are developed based on the following six considerations:

- risk insights from plant specific PRAs
- industry experience
- consistency with the quantitative

guidelines identified in the framework document

- reasonable cost burden
- proven technology
- suitability for performance-based compliance monitoring

The potential changes derived from both approaches are evaluated to arrive at the risk-informed alternative.

5.2.1 Revising Current Requirements Approach

The approach based on revising the existing technical requirements is shown in Figure 5-3. Each of the six steps in this approach is described below.

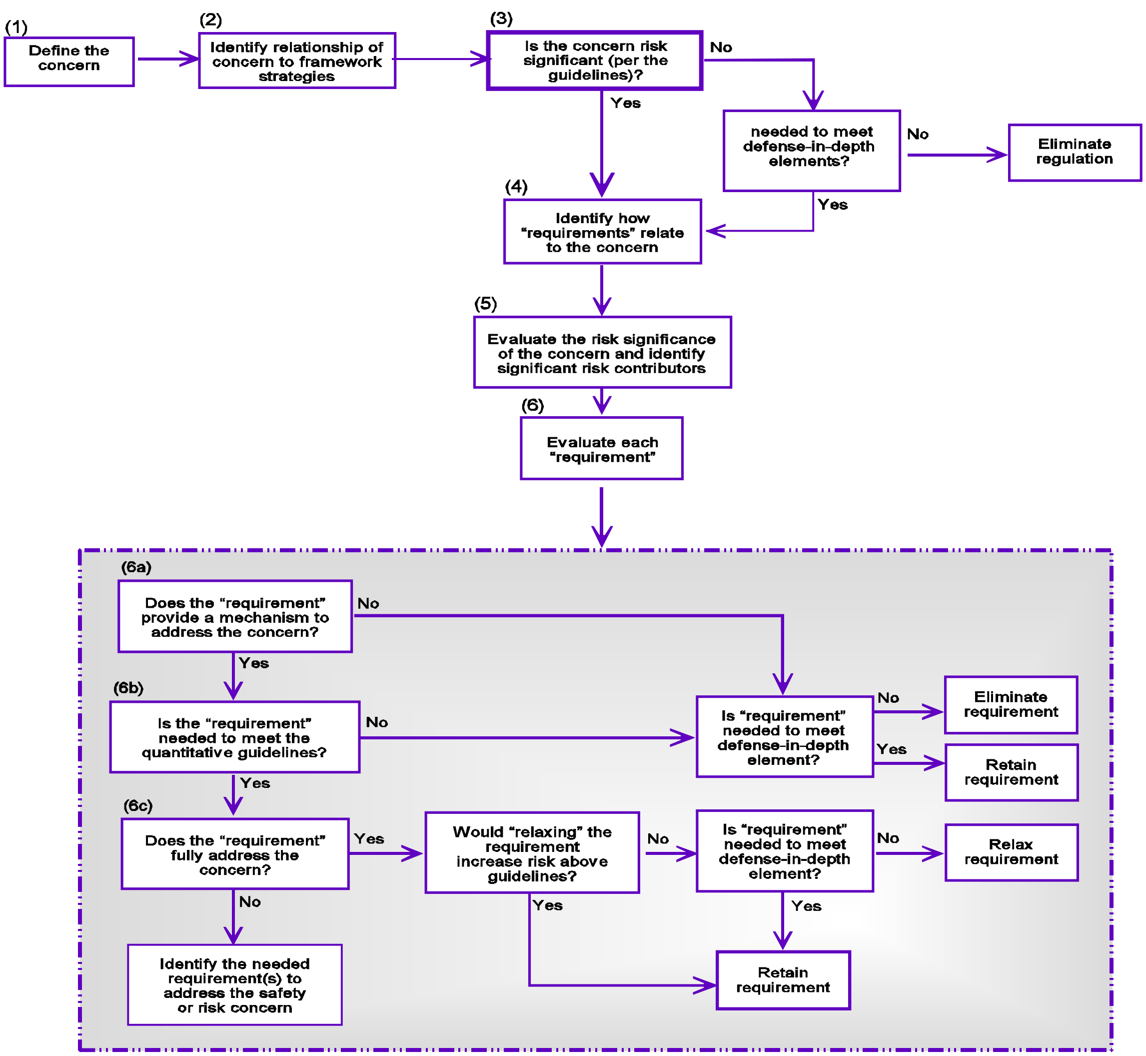

Figure 5-3 Current Requirements Approach to Develop Risk-Informed Changes

(1) Define the concern:

As mentioned previously, development of risk-informed changes to the technical requirements of a regulation begins with an examination of the concern or concerns that necessitated the regulation. Only after the concern is clearly understood, can a determination be made as to how risk-significant the concern is, and how effectively the concern is addressed by the existing requirements. The concern should be expressed in terms of its risk significance (e.g., which risk-significant accidents are impacted, and how significant is this impact).

(2) Identify relationship of concern to framework strategies:

In Section 2 of this report, four defense-in-depth strategies to be considered in making risk-informed change to the regulations were identified. Two of these strategies are preventive (limit frequency of accident initiators and limit probability of core damage given an initiator), and two of the strategies are mitigative (limit radionuclide releases given core damage and limit public health effects given release). The next step in developing risk-informed changes is to identify which of the four strategies are impacted by the concern.

(3) Is the concern risk significant (per the guidelines)?

The risk significance of the concern is assessed against the quantitative guidelines in Figure 3-1. Based on information derived from PRAs, an assessment of the quantitative significance of the concern is made with respect to the quantitative guidelines presented in Figure 3-1 for various types of plants (as defined by their nuclear steam supply systems or containment designs). If the risk significance of the concern results in values significantly below the quantitative guidelines, then the regulation (in its entirety) may become a candidate for elimination. Such regulations must be evaluated to determine (1) if the low risk is because of the technical requirements imposed by the regulation, and if not, then (2) whether the technical requirements are needed to meet any of the defense-in-depth elements. If it is determined that they are not needed to meet the guidelines nor are they needed to maintain defense-in-depth, then the regulation itself becomes a candidate for elimination. It is important to note that all candidates for elimination identified through this process (which is derived with basis on the four reactor safety cornerstones) will also be examined to assure that their elimination will not have any adverse impact on AOOs and the radiation safety and security cornerstones.

(4) Identify how "requirements" relate to the concern:

Each technical requirement contained in the existing regulation is identified and described in detail in terms of the affected systems, structures, components and procedures (if any) for the various types of plants and the criteria used for assessing compliance with the requirements. A review is then made to determine the relationship of each requirement to other regulations and implementing documents, such as regulatory guides, standard review plan, branch technical positions, generic letters, etc. The purpose of this review is to obtain a detailed understanding of the implications of revising any particular requirement in terms of its impact across the body of the regulations and implementing documents.

Subsequent to the above review, the basis and method of implementation of the requirements by industry are identified and described. A determination is made as to whether the requirement has been implemented by the licensees on the basis of the regulation alone, on the basis of an associated regulatory guide or other implementing document, or on some other basis.

Lastly, each requirement identified at the beginning of this step is evaluated in the context of how effectively it addresses the defined concern.

(5) Evaluate the risk significance of the concern and identify significant risk contributors:

This step is essentially a detailed extension of step (3), above. In step (3), the risk significance of the concern was evaluated, at a high level, in comparison with the quantitative guidelines provided in Figure 3-1. Given that the concern was determined to be risk-significant in step (3), in this step, available PRA information (e.g., NUREG-1150, or IPEs) is reviewed to determine what is driving the risk-significance of the concern. For the various types of plants (as defined by their nuclear steam supply systems or containment designs), the risk significant contributors are identified, where possible, in terms of the PRA results (e.g., dominant accident sequences, or dominant containment failure modes).

(6) Evaluate the each requirement:

In this step, each technical requirement identified in step (4) is evaluated to determine if, and how, it should be risk-informed. Options for risk-informed changes to the technical requirements broadly fall into the following three categories:

- eliminate the current requirement
- retain the current requirement
- revise, enhance, or supplant the current requirement

Guidance as to which category each requirement falls into is provided by answering the three questions described below.

6a Does the requirement provide a mechanism to address the concern?

The answer to this question should have been obtained during step (4) above. If the requirement does not provide a mechanism to address the concern, then it should be evaluated to determine whether it is needed to meet any of the defense-in-depth elements. If it is determined that the requirement is needed to maintain defense-in-depth, then the requirement is retained. However, if it is determined that the requirement is not needed to maintain defense-in-depth, then it becomes a candidate for elimination. It is important to note, as before, that all requirements that are identified as candidates for elimination through this process will also be examined to assure that their elimination will not have any adverse impact on the radiation safety and security cornerstones.

If the requirement does provide a mechanism to address the concern, then it is subjected to the following question.

6b Is the requirement needed to meet the quantitative guidelines?

Based on information obtained in steps (3-5), a determination is made as to whether the requirement is necessary in order for the strategies impacted by the concern to meet the associated quantitative guidelines provided in Figure 3-1. If the requirement is determined not to be necessary to meet the quantitative guidelines, then it will be either eliminated or retained based on whether it is needed to meet any of the defense-in-depth elements, as discussed for the previous question. If the requirement is determined to be necessary to meet the quantitative guidelines, then it is subjected to the following question.

6c Does the requirement fully address the *concern?*

This question is used to determine whether or not a safety enhancement would be appropriate. It is possible that there are aspects of the defined concern which are not fully addressed by the existing requirement (or requirements). In this case, any necessary additional requirements should be identified, so that the concern will be fully addressed.

If the requirement does fully address the concern, then the requirement is evaluated to determine whether or not it can be relaxed and still maintain risk below the quantitative guidelines. If relaxing the requirement would increase risk above the guidelines, then the requirement is retained, as is. If relaxing the requirement would still maintain risk below the guidelines, then it can be relaxed, as long as it is not needed to meet any of the defense-in-depth elements, as discussed previously.

5.2.2 Developing Alternative Requirements Approach

As noted above the main difference between the two approaches to developing risk-informed changes is that risk-informed changes obtained through implementation of the alternative requirements approach are developed without reference to the existing technical requirements of the regulation. In this approach, as seen from Figure 5-4, risk-informed changes for addressing the concern can be identified during any of steps (2-4). This allows changes to be developed from different perspectives. The four steps in an alternative approach that begins afresh from a risk-informed perspective are described below using the four strategies of the framework and with again defining the concern.

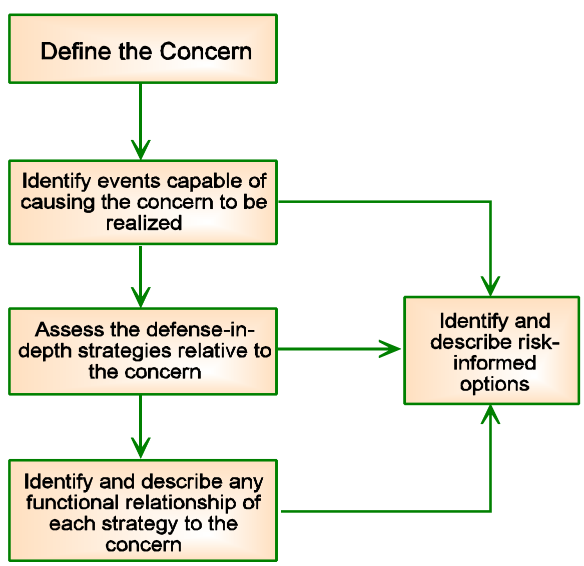

Figure 5-4 Alternative requirements approach to developing risk-informed options

(1) Define the concern:

This step is very similar to step (1) for the revising current requirements approach. As mentioned previously, development of risk-informed changes to a regulation begins with an examination of the concern or concerns that necessitated the regulation. The concern should be expressed in terms of its risk significance (e.g., which risk-significant accidents are impacted, and how significant is this impact).

(2) Identify events capable of causing the concern to be realized:

After the concern is defined, an identification is made at a high-level of events that could cause the concern to be realized. For example, if the concern is that a deflagration/detonation of combustible gas could threaten containment, for the concern to be realized there must be generation of combustible gas from metal-water reactions during an accident in which significant core damage occurs. If the concern is that rupture of a large pipe in the reactor coolant system could threaten public health and safety, for the concern to be realized emergency core cooling and containment functions would also have to fail. Existing PRAs can, generally, provide more specific insights regarding specific sequences of events that are most likely to cause an identified concern to be realized.

(3) Assess the defense-in-depth strategies relative to the concern:

As mentioned previously, Section 2 of this report identifies four defense-in-depth strategies for limiting accident risk. Three of these strategies also have quantitative guidelines associated with them, as shown in Figure 3-1. In this step, the efficacy of each strategy relative to preventing and mitigating the identified concern is assessed. For those strategies that address the concern, performance-based options can be developed with high-level acceptance criteria, which would allow licensees substantial flexibility in meeting them. In addition, if it is anticipated that it may be difficult for licensees to meet the high-level acceptance criteria based on the strategies that address the concern, similar type options can be developed based on the remaining strategies. For example, the reduction of the frequency of an accident class under which the concern becomes less manageable may be more practical than ensuring the operability of a mitigating system under the same conditions.

(4) Identify and describe any functional relationship of each strategy to the concern:

Understanding the functional relationships between each strategy and the concern allows practical methods of applying each defense-in-depth strategy to the defined concern to be identified, for relevant plant types. These changes are expected to be much more prescriptive than those developed under the preceding step. For example, specific hardware or procedures may be identified in these changes for applying a specific strategy to the concern. As in the previous step, the changes may relate to the strategies that address the concern, or it may prove to be more practical to develop changes related to the other strategies. For example, station blackout accidents may impose the most severe conditions on the plant's ability to successfully control combustible gas concentrations. An option reducing the frequency of station blackout may prove to be more practical for managing the defined concern than attempting to ensure that mitigating systems can successfully operate under station blackout (SBO) conditions.

5.3 Step 3: Evaluation of Risk-informed Alternative

In the previous step, all changes were developed based on safety and risk implications with consideration of the defense-in-depth elements. These changes were evaluated to arrive at a risk-informed alternative to an existing regulation. In this step, the risk-informed alternative is evaluated in order to estimate the associated NRC and licensee burdens, for both implementing and applying the alternative, and to compare these estimates with similar estimates for the existing regulation. The factors affecting both NRC and licensee burden are provided below.

Factors impacting NRC:

- **Need for a rule change —** The formal rule-making process can involve a substantial expenditure of resources by the NRC. Therefore, whether or not a proposed risk-informed alternative necessitates a change to the regulation itself is an important consideration in determining the NRC burden.

- **Impact on other regulations —** Due to the interrelationship of various regulations, changes to one regulation may require corresponding changes in other regulations, which can increase the burden to the NRC. Regulations that do not have a relationship with other regulations can be addressed unilaterally in the risk-informed process.

- **Need to revise or modify implementing documents —** In order to implement an option, it may be necessary to revise or modify one or more implementing documents (e.g., regulatory guides or standard review plan sections). Modifications to the implementing documents may represent the sole change associated with the risk-informed alternative, or these changes may be in conjunction with changes to the regulation (or regulations).

- **Need to create a new implementing document —** In some instances, a new implementing document may need to be developed. Development of the implementing document may or may not be in conjunction with changes to the regulation (or regulations), and may or may not be in conjunction with modifications to other implementing documents.

- **Extent of regulatory analysis required —** The extent of regulatory analysis required in support of a risk-informed alternative may range from virtually none, if existing information and analysis results satisfactorily address the safety benefit and NRC and licensee burdens associated with the risk-informed alternative, to substantial, if significant resources need to be expended to evaluate previously unanalyzed aspects of the risk-informed alternative .

- **Need for NRC review of licensee submittals —** If the particular aspects of a risk-informed alternative require that each licensee provide a submittal to the NRC, then the associated NRC review costs need to be considered.

- **Impact on NRC inspection activities —** Consideration needs to be given to the impact, if any, that a particular risk-informed alternative has on NRC inspection activities. The nature of this impact may be to increase the burden associated with NRC inspection activities, or to decrease the burden.

Factors impacting Licensees:

- **Need for new or modified equipment —** As a result of a particular option, the need for the licensee to remove, install, replace or modify existing plant equipment can be a contributor to licensee burden. In some cases, replacement of equipment (when necessary) may result in a decrease in licensee burden, if the risk-informed alternative allows replacement equipment of a lower pedigree than the existing equipment.
- **Need for analysis —** Consideration is given to the need for, and extent of, any

analysis required to be performed by the licensee. For example, if use of a PRA is required, then there may be burden associated with modifying the PRA to meet a given level of completeness and confidence. Also, consideration needs to be given to the burden associated with documentation and reporting requirements associated with the specified analysis.

- **Impact on maintenance and inspection activities —** Consideration needs to be given to the impact, if any, that a particular risk-informed alternative has on licensee inspection and maintenance activities. The nature of this impact may be to increase or decrease the burden associated with these activities.

- **Impact on technical specifications —** Consideration needs to be given to the impact, if any, that a particular risk-informed alternative has on plant technical specifications. This impact, which can either increase or decrease burden, may involve such things as system or equipment testing frequencies, or conditions for which the plant must shut down.

- **Impact on procedures and training —** Consideration needs to be given to the impact, if any, that a particular risk-informed alternative has on plant procedures and training. If a particular risk-informed alternative requires plant procedures to be changed or written, consideration must be given to the cost of modifying or writing the procedures, as well as to the cost of the associated operator training to become familiar with the new procedures.

6.0 SUMMARY

This document presents a framework and guidelines to be used in making risk-informed changes to the existing technical requirements of 10 CFR 50. The approach maintains four high-level defense-in-depth functions, which support the protection of the public health and safety goal and are consistent with the reactor safety cornerstones developed for regulatory oversight. Risk information is used to evaluate the effectiveness of the defense-in-depth approach. Although regulations will be revised or originated based on risk information, they will retain deterministic characteristics. The development of risk-informed regulatory requirements will be guided by quantitative safety objectives, insights derived from PRAs and IPEs, and the need to account for uncertainty, particularly in cases where one or more of the high-level defense-in-depth functions is precluded.

7.0 REFERENCES

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

2. USNRC, SECY-98-300, "Options for Risk-informed Revisions to 10 CFR 50 - 'Domestic Licensing of Production and Utilization Facilities,'" December 23, 1998.

3. USNRC, SECY-99-264, "Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50," November 8, 1999.

4. USNRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, November, 1995.

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

6. USNRC, "Safety Goals for the Operation of Nuclear Power Plants; Policy Statement," *Federal Register*, Vol. 51, p. 30028, August 21, 1986.

7. USNRC, "New NRC Reactor Inspection and Oversight Program," NUREG-1649, Rev. 1, May 1999.

8. Letter from D. A. Powers, Chairman, Advisory Committee on Reactor Safeguards, to The Honorable Shirley Ann Jackson, Chairman, U. S. Nuclear Regulatory Commission, "The Role of Defense in Depth in a Risk-Informed Regulatory System," May 19, 1999.

9. J. N. Sorensen, G. E. Apostolakis, T. S. Kress, D. A. Powers, "On the Role of Defense in Depth in Risk-Informed Regulation," Presented at PSA‹99, Washington, D.C., August 22-25, 1999.

10. USNRC, "New NRC Reactor Inspection and Oversight Program," NUREG-1649, Rev. 1, May 1999.

11. USNRC, SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," January 8, 1999.

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

13. E. B. Haugen, *Probabilistic Approaches to Design*, John Wiley & Sons, Inc., London, 1968.

14. Letter from Joe F. Colvin, President, Nuclear Energy Institute, to Richard A. Meserve, Chairman, U.S. Nuclear Regulatory Commission, January 19, 2000.

APPENDIX A

COARSE SCREENING OF
10 CFR 50 AND 100

TABLE OF CONTENTS

LIST OF TABLES

APPENDIX A

A.1 Coarse Screening of Part 50

Based on a preliminary review, out of a total of 82 regulations and 17 published Appendices under Part 50, the following 57 regulations and 8 Appendices, as listed below in Table A-1, have no relevance to risk-informing.

Table A-1 Part 50 Regulations and Appendices that have no relevance to Risk-Informing

General Provisions	
50.1	Basis, purpose, and procedures applicable
Requirement of License, Exceptions	
50.10	License required.
50.11	Exceptions and exemptions from licensing requirements.
50.13	Attacks and destructive acts by enemies of the United States; and defense activities.
Classification and Description of Licenses	
50.20	Two classes of licenses.
50.21	Class 104 licenses; for medical therapy and research and development facilities.
50.22	Class 103 licenses; for commercial and industrial facilities.
50.23	Construction permits.
Applications for Licenses, Form, Contents, Ineligibility of Certain Applicants	
50.30	Filing of applications for licenses; oath or affirmation.
50.31	Combining applications.
50.32	Elimination of repetition.
50.33a	Information requested by the Attorney General for antitrust review.
50.34a	Design objectives for equipment to control releases of radioactive material in effluents -- nuclear power reactors.
50.35	Issuance of construction permits.
50.36a	Technical specifications on effluents from nuclear power reactors.
50.36b	Environmental conditions.
50.37	Agreement limiting access to Restricted Data.
50.38	Ineligibility of certain applicants.
50.39	Public inspection of applications.

Table A-1 Part 50 Regulations and Appendices that have no relevance to Risk-Informing

Standards for Licenses and Construction Permits	
50.40	Common standards.
50.41	Additional standards for class 104 licenses.
50.42	Additional standards for class 103 licenses.
50.43	Additional standards and provisions affecting class 103 licenses for commercial power.
50.45	Standards for construction permits.
Issuance, Limitations, and Conditions of Licenses and Construction Permits	
50.50	Issuance of licenses and construction permits.
50.51	Continuation of license.
50.52	Combining licenses.
50.53	Jurisdictional limitations.
50.55	Conditions of construction permits.
50.56	Conversion of construction permit to license; or amendment of license.
50.57	Issuance of operating license.
50.58	Hearings and report of the Advisory Committee on Reactor Safeguards.
50.64	Limitations on the use of highly enriched uranium (HEU) in domestic non-power reactors.
Inspections, Records, Reports, Notifications	
50.70	Inspections.
50.71	Maintenance of records, making of reports.
50.72	Immediate notification requirements for operating nuclear power reactors.
50.74	Notification of change in operator or senior operator status.
50.75	Reporting and record keeping for decommissioning planning.
US/IAEA Safeguards Agreement	
50.78	Installation information and verification.
Transfers of Licenses -- Creditors' Rights -- Surrender of Licenses	
50.80	Transfer of licenses.
50.81	Creditor regulations.
50.82	Termination of license.
Amendment of License or Construction Permit at Request of Holder	
50.90	Application for amendment of license or construction permit.
50.91	Notice for public comment; State consultation.

Table A-1 Part 50 Regulations and Appendices that have no relevance to Risk-Informing

Revocation, Suspension, Modification, Amendment of Licenses and Construction Permits, Emergency Operations by the Commission	
50.100	Revocation, suspension, modification of licenses and construction permits for cause.
50.101	Retaking possession of special nuclear material.
50.102	Commission order for operation after revocation.
50.103	Suspension and operation in war or national emergency.
Enforcement	
50.110	Violations.
50.111	Criminal penalties.
50.120	Training and qualification of nuclear power plant personnel.
Appendix C:	A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Facility Construction Permits
Appendix F:	Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities (Not relevant to reactors)
Appendix H:	Reactor Vessel Material Surveillance Program Requirements
Appendix I:	Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents (applicable to routine emissions)
Appendix L:	Information Requested by the Attorney General for Antitrust Review of Facility License Applications
Appendix M:	Standardization of Design; Manufacture of Nuclear Power Reactors; Construction and Operation of Nuclear Power Reactors Manufactured Pursuant to Commission License
Appendix N:	Standardization of Nuclear Power Plant Designs: Licenses to Construct and Operate Nuclear Power Reactors of Duplicate Design at Multiple Sites
Appendix O:	Standardization of Design: Staff Review of Standard Designs

The remaining 23 regulations and 9 Appendices to Part 50, as listed below in Table A-2, have a potential relevance to the risk-informed process. The relevance, however, may only be indirect or partial in some cases. As mentioned above, a second screening will need to be carried out to determine those that have a direct relevance to accident prevention and/or mitigation.

Table A-2 Part 50 Regulations potentially relevant to Risk-Informing

50.2	Definitions
50.12	Specific exemptions.
50.33	Contents of applications; general information.
50.34	Contents of applications; technical information
50.36	Technical specifications.
50.44	Standards for combustible gas control system in light-water-cooled power reactors.
50.46	Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.
50.47	Emergency plans.*
50.48	Fire protection.*
50.49	Environmental qualification of electric equipment important to safety for nuclear power plants.
50.54	Conditions of licenses.
50.55a	Codes and standards.
50.59	Changes, tests and experiments.
50.60	Acceptance criteria for fracture prevention measures for lightwater nuclear power reactors for normal operation.
50.61	Fracture toughness requirements for protection against pressurized thermal shock events.*
50.62	Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.
50.63	Loss of all alternating current power.
50.65	Requirements for monitoring the effectiveness of maintenance at nuclear power plants. (Eff. July 10, 1996)
50.66	Requirements for thermal annealing of the reactor pressure vessel.
50.68	Criticality accident requirements.
50.73	License event report system.
50.92	Issuance of amendment.
Appendix A:	General Design Criteria for Nuclear Power Plants
Appendix B:	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
Appendix E:	Emergency Planning and Preparedness for Production and Utilization Facilities (Partly relevant if EP for advanced reactors is different based on risk)
Appendix G:	Fracture Toughness Requirements (Maybe relevant)
Appendix J:	Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors
Appendix K:	ECCS Evaluation Models
Appendix Q:	Pre-application Early Review of Site Suitability Issues (Partly relevant)
Appendix R:	Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979
Appendix S:	Earthquake Engineering Criteria for Nuclear Power Plants (Partly relevant)

*50.47, 50.48 and 50.61 are not part of the scope of this effort; these regulations are being addressed under other programs.

A.2 Coarse Screening of Part 100

Part 100, "Reactor Site Criteria", deals with the factors that influence the approval of a site for locating and constructing a nuclear power plant and the criteria to be used in arriving at a decision on site selection. Public health and safety and the development of emergency plans are cited as important criteria in this regard and it is stated in Part 100.1 "Purpose" that "the primary factors that determine public health and safety are reactor design, construction, and operation." This implies that the provisions of Part 100, like those of Part 50, are also suitable candidates for risk-informing.

Part 100 was significantly revised in December 1996 to reflect information derived from risk-oriented studies of the siting of nuclear power plants [4,5]. Other objectives [6] of the revision were to provide a stable regulatory basis for seismic and geologic siting and applicable earthquake engineering design of future nuclear power plants and to decouple siting criteria from design by relocating the source term and dose requirements that apply primarily to plant design into Part 50.

Part 100.1 "Purpose", Part 100.2 "Scope", and Part 100.3 "Definitions" were changed. A new Subpart B "Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997" was added consisting of new paragraphs 100.20 "Factors to be considered when evaluating sites", 100.21 "Non-seismic siting criteria" and 100.23 "Geologic and seismic siting criteria". (However, the old Appendix A to Part 100 that defined the seismic and geologic siting criteria earlier has been retained unchanged. It is stated to apply to an operating license applicant or holder whose construction permit was issued prior to January 10, 1997). The older Parts 100.10 and 100.11 are now placed under Subpart A "Evaluation Factors for Stationary Power Reactor Site Applications Before January 10, 1997 and for Testing Reactors".
The same criteria that were applied to the Part 50 regulations have been applied to Part 100 to subdivide them into the 2 categories, Category 1 and Category 2, defined above. It should be noted that Parts 100.10, 100.11 of Subpart A and Appendix A to Part 100 now refer specifically to power reactor site applications received before January 10, 1997 or to testing reactors. If there are no operating license applicants or holders with construction permits issued prior to 1/10/97 who are currently seeking approval for a site to construct a commercial nuclear power plant, then it would appear that Subpart A is essentially moot. In principle, Parts 100.10 and 100.11 and Appendix A should be candidates for risk-informing.

Table A-3 Part 100 Regulations that have no relevance to Risk-Informing

100.3	Communications
100.8	Information collection requirements: OMB approval

Table A-4 Part 100 Regulations potentially relevant to Risk-Informing

100.1	Purpose
100.2	Scope
100.3	Definitions
100.10	Factors to be considered when evaluating sites
100.11	Determination of exclusion area, low population zone, and population center distance
100.20	Factors to be considered when evaluating sites
100.21	Non-seismic siting criteria
100.23	Geologic and seismic siting criteria
Appendix A:	Seismic and Geologic Siting Criteria for Nuclear Power Plants