DRAFT ACTION PLAN

STABILIZING THE PRA QUALITY EXPECTATIONS AND REQUIREMENTS

draft

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1.0 INTRODUCTION

1.1 Background

The Commission believes that an overall policy on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities should be established so that the many potential applications of PRA would be implemented in a consistent and predictable manner that would promote regulatory stability and efficiency. In addition, the Commission believes that the use of PRA technology in NRC regulatory activities should be increased to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach. With implementation of this policy statement, the Commission also recognizes, and encourages, continuation of industry initiatives to improve PRA methods, applications and data collection to support increased use of PRA techniques in regulatory activities.

Since the PRA Policy Statement (Ref. 1) was issued, a number of risk-informed activities have been undertaken and a number of documents have been written by both the staff and industry that provide guidance on (1) the use of PRA information in the risk-informed reactor regulatory activities, and (2) on PRA quality. These include:

- At NRC, regulatory guidance documents have been written to address risk-informed applications that use PRA information. These include Regulatory Guide 1.174 (Ref. 2) and Standard Review Plan (SRP) Chapter 19 (Ref. 3), which provide general guidance on applications that address changes to the licensing basis. Key aspects of these two documents that are common to both are:

  — Each relates to a "risk-informed integrated decision-making" process that characterizes how risk information is used, and, more specifically, that such information is one element of the decision-making process. That is, decisions "are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information."

  — Each reflect the staff's recognition that the PRA needed to support regulatory decisions can vary, i.e., that the "scope, level of detail, and quality of the PRA is to be commensurate with the application for which it is intended and the role the PRA results play in the integrated decision process." General guidance regarding scope, level of detail, and quality for a PRA is provided.

  — Each is written in the context of one reactor regulatory activity (license amendments), but the underlying philosophy and principles are applicable to a wide spectrum of reactor regulatory activities.

  In addition, for specific applications, guidance is provided in separate regulatory guides for such applications as inservice testing (Ref. 4), inservice inspection (Ref. 5), quality assurance (Ref. 6), and technical specifications (Ref. 7). SRP chapters were also prepared

for each of the application-specific regulatory guides with the exception of quality assurance.

- Reactor owners' groups have been developing and applying a PRA peer review program for several years. In a letter dated April 24, 2000, the Nuclear Energy Institute (NEI) submitted NEI-00-02 (Ref. 8) to the NRC for review in the context of the staff's work to risk-inform the scope of special treatment requirements contained in 10 CFR Part 50 (discussed in SECY-99-256 -Ref. 9).

  On August 16, 2002, NEI submitted draft industry guidance for self-assessments (Ref. 10) to address the use of industry peer review results in demonstrating conformance with the ASME PRA standard. This additional guidance, which is intended to be incorporated into a revision of NEI-00-02 (per NEI, see Reference 10), contains:

  — Self assessment guidance document
  — Appendix 1 – actions for industry self assessment
  — Appendix 2 – industry peer review subtier criteria

- PRA standards have been under development by the American Society of Mechanical Engineers (ASME) and American Nuclear Society (ANS). On April 5, 2002, ASME issued a standard for a full-power, internal events (excluding fire) Level 1 PRA and a limited Level 2 PRA (Ref. 11). In December 2003, ANS issued a standard for external events (Ref.12). In the future, ANS plans to issue standards for PRAs for evaluating internal fire risk and risk from low power and shutdown modes of operation.

- SECY-02-0176 (Ref. 13) discusses, in a proposed draft regulatory guide DG 1121, how References 8, 10 and 11, together with a regulatory guide to address PRA quality (since published as RG 1.200), could be used in the context of the proposed new rule (i.e., 50.69) for risk-informing the special treatment requirements of 10 CFR Part 50.

- In the March 31, 2003 Staff Requirements Memorandum (SRM) (Ref. 14), the Commission directed the staff to undertake several rulemakings, and stated that the redefinition of the LBLOCA would require a high quality PRA, including low power and shutdown operations. They further stated that "Once the appropriate standards are in place, the PRA should be a Level 2 internal- and external-initiating event all mode PRA, which has been subjected to a peer review process and submitted to and endorsed by the NRC".

- RG 1.200 (Ref. 15), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued for trial use, provides guidance in four areas:

  (1) A minimal set of functional requirements of a technically acceptable PRA.

  (2) NRC position on consensus PRA standards and industry PRA program documents (Currently, Appendix A contains the staff position on the ASME standard for a Level 1 and limited Level 2 (large early release frequency) PRA for internal events

(excluding fires) and only addresses full power operation, and Appendix B contains the staff position on the industry peer review and self-assessment process.)

(3) Demonstration that the PRA (*in toto* or specific parts) used in regulatory applications is of sufficient technical adequacy.

(4) Documentation to support a regulatory submittal.

RG 1.200 is expected to provide the level of confidence that the technical quality of the PRA is adequate to support the identified applications such that an in-depth technical review by NRC staff would not be needed to ensure its quality to support the applications. This RG will allow staff to focus their review on key assumptions and areas identified by peer reviewers as being of concern, that are relevant to the application. Consequently, RG 1.200 will provide for a more focused and consistent review process.

On December 18, 2003, the Commission provided a SRM (Ref. 16) regarding stabilizing PRA quality expectations and requirements. In the SRM, the Commission approved implementation of a phased approach to achieving an appropriate quality for PRAs for NRC's risk-informed regulatory decisionmaking. This phased approach was described in an attachment to the SRM. The SRM also directed the staff to develop an action plan that would define a practical strategy for the implementation of the phased approach to PRA quality. This document provides that action plan.

1.2 Objectives

1.2.1 Phased Approach Objectives

The objective of the phased approach to stabilizing the PRA quality expectations and requirements is to achieve an appropriate level of PRA quality for NRC's risk-informed regulatory decisionmaking. That is, the phased approach defines the needed PRA quality for all envisioned applications and the process for achieving this quality while the necessary guidance documents defining the PRA quality are developed and implemented.

It is expected that meeting the phased approach objective will result in the following:

- Industry movement towards improved and more complete PRAs
- Increased efficiencies in the staff's review of risk-informed applications
- Clarification of expectations for 10CFR50.46 and 10CFR50.69 rulemakings
- Continued near-term progress in enhancing safety through the use of available risk-informed methods while striving for increased effectiveness and efficiency in the longer term.

An additional objective is to ensure that activities are coherently and properly integrated such that they complement one another and continue to meet the 1995 Commission's Policy Statement.

1.2.2 Plan Objectives

The objectives of this document are to provide the action plan for implementation of the phased approach and to describe how the objectives stated above will be accomplished. The plan describes the phased approach and what activities, on the part of both NRC and industry, are needed to achieve the program objectives. In addition, the action plan discusses the resolution of the following technical issues: model uncertainty; treatment of seismic and other external events; and human performance issues. As a result of implementing the plan, other technical issues needing resolution may be identified.

1.3 Scope and Limitations

The approach in this plan is based on the attachment to the December 18, 2003, SRM (Ref. 15) and addresses current risk-informed ***reactor*** activities (involving licensing changes and risk-informing Part 50) and the associated guidance documents supporting these activities. Risk-informed activities addressing nuclear materials are not addressed in this plan.

2.0 THE PHASED APPROACH

The Commission, in Reference 15, introduced the concept of a four phased approach to PRA quality that provides a pathway for the continued practical use of risk-informed methods and continued progress towards adoption of state-of-the-art methodologies. This phased approach is needed because not all the guidance documents defining PRA quality are available for all the risk contributors. This approach lays out a path, in a phased manner, how risk-informed applications can be implemented while the needed guidance documents defining PRA quality for the risk contributors are developed. Throughout this paper, as in RG 1.200, the quality of a PRA analysis used to support a specific application is measured in terms of its appropriateness with respect to scope (in terms of contributors to risk), level of detail, and technical acceptability.

Only the first three phases are included in this plan, as required by the SRM. Resources for pursuing Phase 4 will be evaluated after Phase 2 and Phase 3 have established a functional framework.

In this chapter, the three phases are defined, the activities needed to achieve each phase are defined, and the proposed implementation of these phases is described.

2.1 Definition of the Phases

In this section, a definition of each phase is provided. Each phase is characterized in terms of the available guidance documents relative to the risk-informed activities. It is the availability and implementation of technical guidance documents that address the PRA scope and level of detail necessary to support an application that distinguishes the phases. In addition, another distinction between the phases is the type and priority of the staff review. The staff review mat be based on

"formal" review guidance or a more "ad hoc" review (formal guidance is not available) and the review may receive either a higher or lower priority status.

The required PRA scope is defined in terms of the:

- Risk metric used in the decision (e.g., CDF, LERF, health effects) and whether a Level 1, 2, or 3 PRA is required
- Coverage of initiating events (internal events, external events)
- Plant operational modes impacted by the application (full power, low power and shutdown, transition)

The technical guidance documents are primarily:

- regulatory guides and associated Standard Review Plan Chapters
- PRA Consensus Standards
- Industry PRA Application guides
- NRC generated PRA reference documents (e.g., NUREGs)

At this time, the guidance documents do not cover the above defined PRA scope. Tables 1 and 2 shows the current status (In this draft these tables are not complete and are included for illustrative purposes only).

Table 1 Status of Consensus PRA Standards

ITEM	SCOPE	Responsibility	STATUS
Risk Characterization	Level 1	ASME	available and endorsed in RG 1.200
	Level 2 (LERF)	ASME	available
	Level 2 (full)		
	Level 3		
Operating Modes	Full power	ASME	available
	low power and shutdown	ANS	
Initiating Events	Internal (transients, LOCAs, floods)	ASME	available
	Internal (fires)	ANS	
	external (seismic, winds, floods)	ANS	published under staff review

Table 2 Status of Guidance Documents

APPLICATION	DOCUMENT	RESPONSIBILITY	STATUS
	RG 1.174		
	RG 1.175		
	RG 1.176		
	RG 1.177		
	RG 1.178		
	DG 1121		
	NEI-00-04		
	RG 1.200		
	NEI-00-02		

To implement the guidance documents, some changes to NRC processes and programs will be necessary.

Phase 1: An "Application-Specific" Phase of PRA Quality

Phase 1 corresponds to the current status of the use of PRA in regulatory decision-making. Guidance for using PRA in regulatory decision-making exists in the form of Regulatory Guides (RGs) such as RG 1.174, 1.175, 1.176, and 1.178. These guides address PRA quality in a general way, stating that the quality must be commensurate with the application. They do not, however, provide detailed guidance on what is technically acceptable for the defined scope. The review of applications has been to some extent "ad hoc," (i.e., no formal guidance on PRA technical acceptability). This ad hoc review has, in general, focused on those aspects of the PRA that contribute to the evaluation of the change in the CDF and LERF associated with the application, with particular attention being paid to those aspects of the licensee's PRA that have been identified as potential concerns in previous peer reviews. In this current phase, while all contributors to risk, (i.e., operational modes, and internal and external initiating events) have to be addressed when making the decision, if no PRA exists for some contributors, they may be addressed qualitatively, by bounding methods, compensatory measures, or by defining the change so that the contribution to risk from these missing contributors is not changed.

In the past few years, progress has been made on clarifying the expectations on the technical adequacy of PRAs, which has paved the way for a transition to Phase 2. These include:

- ASME RA-S-2002 Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications, and Addendum 1, issued in December 2003

- NEI-00-02, Probabilistic Risk Assessment Peer Review Process Guidance

- RG 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities

RG 1.200 addresses the use of the ASME and NEI documents as a means for assuring that the PRA used to support an application is technically adequate. However, these documents only address a Level 1 internal events PRA (transients, LOCAs, and internal floods) and a limited Level 2 PRA sufficient to estimate LERF. As shown above in Table 1, other standards are under development to address other contributors to risk.

Phase 2: An "Application Type" Phase of PRA Quality

Phase 2 corresponds to the situation where, for each general application type (such as risk-informed ISI applications, risk-informed Technical Specifications applications, or 10CFR 50.69 applications), the base PRA that supports the application will meet applicable consensus standards, such as the ASME PRA Standard as endorsed in RG 1.200. Furthermore, the PRA scope is such that all operational modes and initiating events that could change the regulatory decision substantially [1]are included in the model quantitatively. Thus, for a specific application type to be considered Phase 2, guidance must be in place for (1) performing the PRA analyses needed to support the application, and (2) assessing that the level of detail and technical adequacy of the PRA models for the significant contributors to risk (i.e., those whose inclusion could change the regulatory decision substantially) is sufficient to support the application.

The staff review in Phase 2 is no longer performed in an "ad hoc" manner, but in a more formal and systematic manner. The review is now based on the appropriate guidance documents relevant to the specific application.

Phase 3: An "All-Applications" Phase of PRA Quality

In Phase 3, the regulatory framework is in place (i.e., guidance documents are available) for all operational modes and initiating events and for all envisioned applications. Therefore, to transition to Phase 3, a licensee would have a PRA that is of sufficient scope (in terms of operational modes and initiating events) to address all currently envisioned applications, and would meet the requirements of all the applicable industry consensus standards.

The staff review in Phase 3 is also is not performed in an "ad hoc" manner, but in a formal and systematic manner. The review is based on the appropriate guidance documents relevant to the specific application. In addition, a one time staff review of the licensee's base PRA can be performed, instead of application specific reviews.

2.2 Activities Needed to Achieve Phases 2 and 3

As discussed above, to fully transition into Phase 2 and then into Phase 3, a number of technical guidance documents need to be developed. Also, as noted above, these guidance documents include:

[1] What this means in practice will be clarified when developing the implementation guidelines (see Section 3.1.4)

- regulatory guides and associated standard review plan chapters
- PRA consensus standards
- Industry PRA Application guides
- NRC generated PRA reference documents (e.g., NUREGs)

The PRA consensus standards provide the requirements for a technically acceptable base PRA (independent of the application) for the defined scope. These standards are endorsed by the staff in Regulatory Guide 1.200.

For each application, there are application-specific regulatory guides (and associated standard review plans), and in some cases, industry developed application-specific guides. These documents provide the application-specific PRA scope. This guidance may be in an industry developed document, and endorsed in the application-specific regulatory guide; or if there is no industry developed guide, this guidance then needs to be added to the application-specific regulatory guide.

For Phase 2, guidance documents only need to be written for each application type, that specify the approach to using the PRA. The guidance documents need to define the scope in terms of contributors to risk (operational modes and initiating events), and specify expectations for level of detail and technical adequacy of the base PRA. Therefore, to fully transition into Phase 2 for a given application type, the following is needed:

- application-specific regulatory guide addressing the PRA application-specific needs
- a standard for performing the PRA for each significant contributor[2]
- staff review and endorsement of the standard(s) in RG 1.200.

Because the standards for different contributors are being developed on different schedules, the transition to Phase 2 status will occur sooner for some application types than it will for others.

For some application types, for example, risk-informed ISI, the associated RGs already exist, but they do not address the PRA application-specific needs. Therefore, they will need to be revised to clarify the application-specific PRA quality requirements once the relevant standards have been developed and endorsed by the staff in a revision to RG 1.200. For other application types, the application-specific PRA guidance is being generated either by the industry and endorsed in a regulatory guide (e.g., NEI-00-04, guidance specifically for 10 CFR 50.69 SSC categorization, is endorsed in DG 1121), or by the staff in the form of regulatory guides and standard review plan chapters. The pace at which the staff's plan can achieve Phase 2 is, therefore, controlled to a large extent by industry development of the necessary standards.

For Phase 3, the staff will develop the necessary guidance to determine that the quality of a PRA is sufficient to support all envisioned applications. For a licensee to achieve Phase 3, it is necessary that the PRA has been developed, and a peer review performed using those quality standards as a basis.

[2] In this context a significant contributor is an operational mode or initiating event type that could change a decision substantially

In addition to the technical guidance documents, NRC processes and procedures will need to be modified, so that the transition between the phases can be accomplished, as discussed below.

2.3 Implementation

The process for NRC staff review of licensee submittals embodied in the phased approach is captured in Figures 2-1 and 2-2. Figure 2-1 shows the distinction between the three phases, and the approach before the Phase 3 guidance is in place. Figure 2-2 shows the approach once all the guidance is in place.

As shown on Figure 2-1, Box 2, once all the guidance documents are available for all envisioned applications, Phase 3 is achieved (go to Figure 2-2). However, since all the guidance documenst are not available at this time, a given application is currently either in Phase 1 or Phase 2. In transitioning from Phase 1 to Phase 2, because different regulatory decisions may require a different scope of PRA, they will transition to Phase 2 at different times. The time at which an application is considered to have transitioned from Phase 1 to Phase 2 is dependent on when the guidance is in place to address the identified contributors for the identified application (Box 4 of Figure 2-1). For example, if an application requires only an internal initiating events PRA, it will be classified as a potential Phase 2 application. A PRA standard exists for internal events and has been endorsed in RG 1.200. If the application-specific regulatory guidance is also available, then the application is potentially in Phase 2. An application that requires a PRA scope that includes a fire PRA, will only become a Phase 2 application when a fire PRA Standard has been issued, RG 1.200 has been revised to include the staff's position on that standard, and the application-specific regulatory guidance is available. In these cases, the applications are a potential Phase 2 because the licensee's base PRA also needs to conform to the standard, at least for the risk-significant contributors (Box 10, Figure 2-1). For the Phase 2 applications (Yes branch of Box 4, Figure 2-1), if the risk-significant contributors are included in the licensee's base PRA, then the application receives a Phase 2 staff review (Box 11, Figure 2-1). An application that does not conform to the Phase 2 expectations, when the guidance for that application type is complete will be considered a Phase 1 application and given low priority if the significant contributors are addressed by alternate means (Box 13, Figure 2-1), or rejected if they are not addressed (Box 9, Figure 2-1).

One subtlety associated with an application is that a licensee can meet the requirements of a Phase 2 application without the full scope identified in the general guidance (e.g., a regulatory guide) as being necessary for that application, but only if the licensee can demonstrate that the missing scope items, for the specific plant and the specific application, would not significantly impact the regulatory decision. For example, if the general guidance states that the contribution of seismic risk should be accounted for, and the standard for a seismic PRA has been endorsed by NRC, a seismic PRA is required for Phase 2, unless the licensee can demonstrate that, because of the location of the plant, and/or because of the seismically robust design of the plant, the seismic risk is negligible. However, this would require staff review of the argument supporting that claim. The NUREG report discussed in Section 3.2.2 will provide characteristics of an acceptable bounding analysis that will assist the staff in the review of the licensee's argument.

For Phase 1 applications (No branch of Box 4, Figure 2-1), there are two cases. The first arises when a licensee uses a PRA which has a scope greater than that for which all the quality guidance

is in place to support the application. This application would require a more extensive staff review of those items (Box 5), without the benefit of quality guidance for some aspects of the application, and thus would be given low priority. The second occurs when the licensee's application uses a PRA that is consistent with current quality guidance (i.e., the PRA scope is the same as that for which guidance has been developed), but the missing scope items are significant for the application. A normal review will be performed as long as the risk contributors are properly addressed (Box 7), and rejected otherwise (Box 9, Figure 2-1) (See also discussion in section 3.1.6).

Figure 2-2 represents that situation when the Phase 3 guidance is complete. Once the guidance for all currently envisioned applications has been developed, a licensee can develop a PRA corresponding to Phase 3 quality. Once a PRA that meets all the quality requirements has been developed (Box 14 of Figure 2-2) there would be no need to address the quality of the base PRA in any future submittal, as long as the submittal was for an application type included in the set for which Phase 3 was defined. At this point, a licensee could prepare documentation, independent of an application, assessing the quality of its PRA, which could be referenced in all future applications.

However, if a new type of application were developed, and it needed new PRA capabilities, that application would be a Phase 1 application until the necessary guidance had been developed. Once the guidance for performing this new application has been developed and endorsed by the NRC, such an application would become a Phase 2 application. Phase 3 would then be revised to include the additional guidance.

Throughout Phase 1, 2 and 3, the staff will continue to use opportunities provided by the risk-informed license application reviews, exercising Phase 3 of the ROP significance determination process, and any benchmarking of NRC models (SPAR, SDP notebooks) to give insights into the technical adequacy of licensee PRAs.

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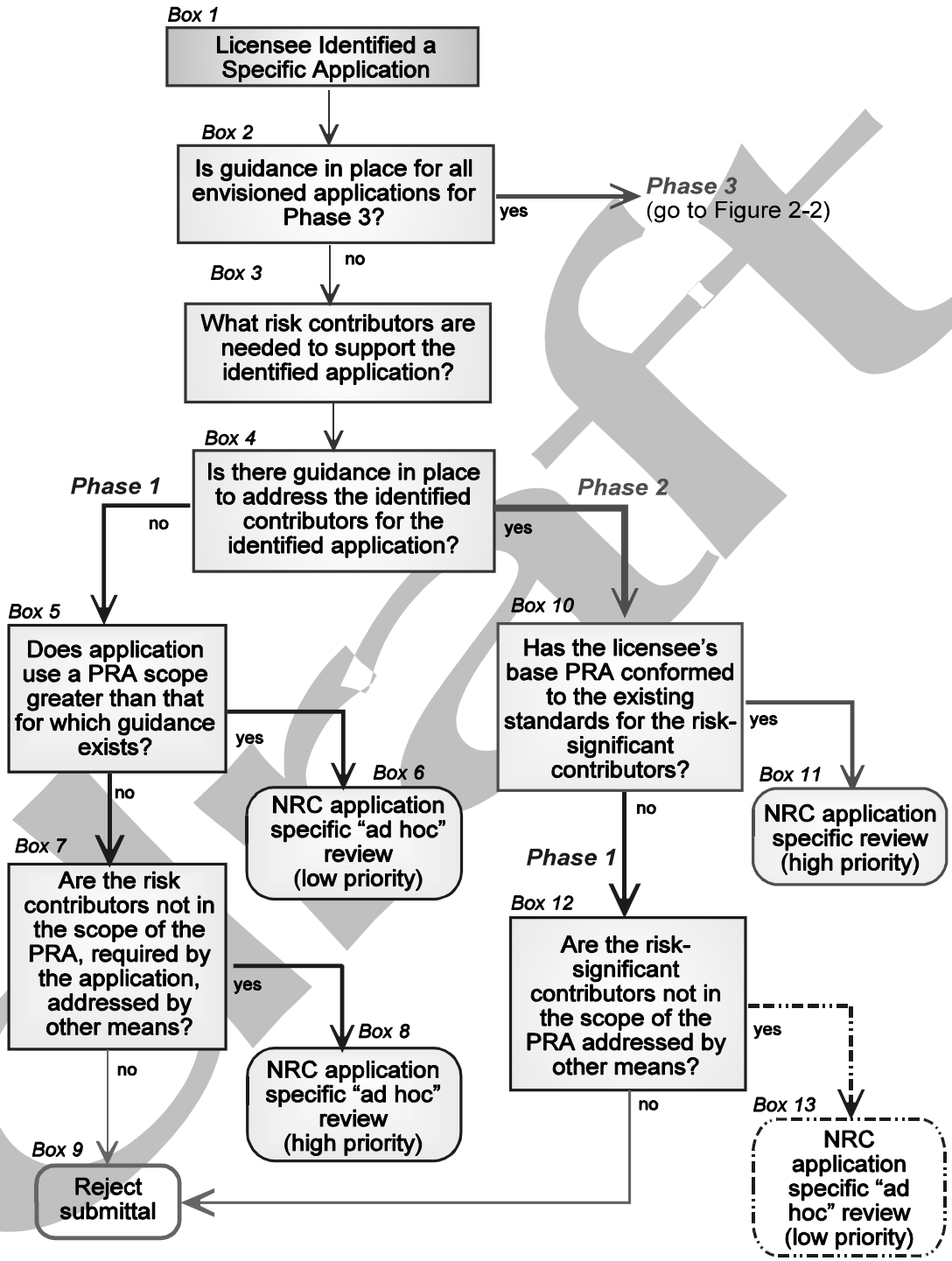

Figure 2-1 Review Process Before Phase 3

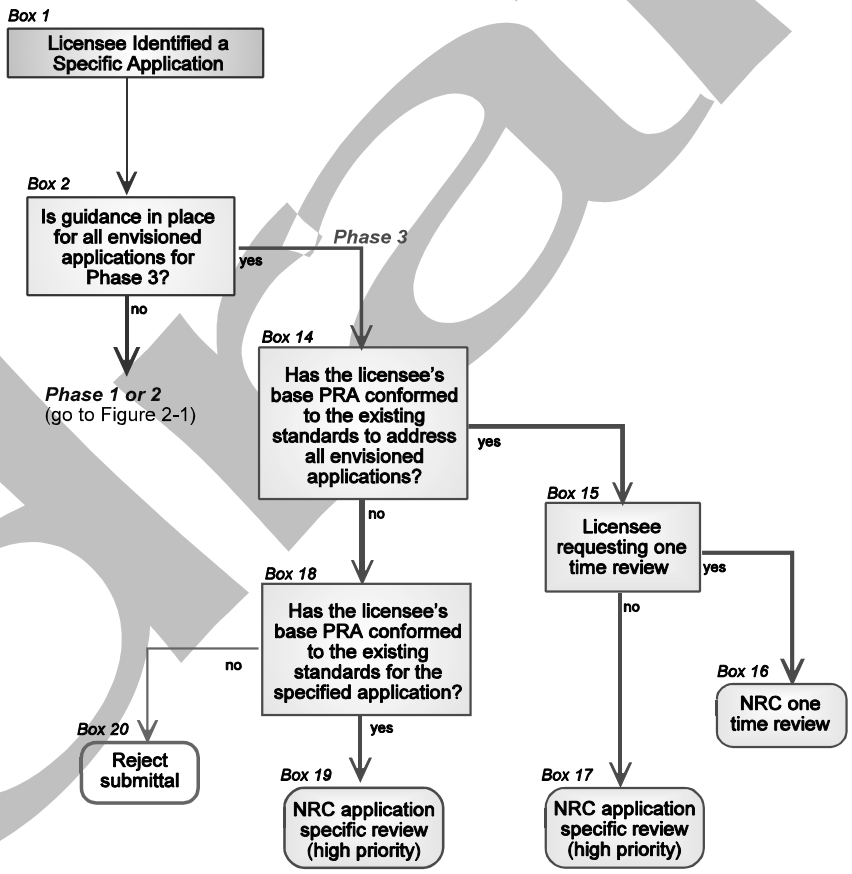

Figure 2-2 Review Process After Phase 3

3.0 APPROACH

This section describes the action plan that defines a practical strategy for implementation of the phased approach to PRA quality. This plan specifically addresses the staff activities to develop the guidance necessary to achieve PRA quality Phases 2 and 3. When the Phase 2 guidance is in place, the expectation is that industry will only submit applications conforming with this guidance.

In addition, the action plan addresses the resolution of technical issues, such as model uncertainty, treatment of seismic and other external events, and human performance issues for each application and phase.

3.1 Implementation of the Phased Approach

Implementation of the phased approach involves seven different tasks:

- Identification of the applications types
- Identification of the Phase 2 guidance documents
- Identification of the staff activities to develop the guidance documents
- The schedule for each application type in Phase 2
- Development of Phase 3 guidance
- Development of implementation guidelines
- Monitoring of PRA quality

The objective of each task and how it will be accomplished are described below.

3.1.1 Task 1: Identify Types of Applications of PRA

The objective of this task is to develop a list of the currently envisioned applications of PRA in the reactor arena. The types of applications include:

- Operational uses, e.g., use by a licensee to support the maintenance rule

- Use of PRA in the Revised Oversight Program (e.g., licensee use of its PRA in Phase 3 of the SDP)

- License amendments, e.g., 50.69, Risk-informed ISI, etc.

- Implementation of new rules e.g., 10 CFR 50.46

For each of the above application types, specific applications will be identified.

3.1.2 Task 2: Identify Guidance Documents Needed for Phase 2

The objective of this task is, for each application type, to identify the role that PRA results make in the decision, and identify the scope and level of detail of the base PRA needed to support that role. Because of the way the decision-making criteria are constructed, some decisions may not

require all the contributors to risk to be addressed. Additionally, since the need for detail, realism, and plant-specificity in the PRA results differs between applications, the capability of PRA in terms of level of detail required will also differ.

For NRC specific programs, such as the reactor oversight program, and the development and use of the SPAR models, an assessment will be made on how best to integrate these programs into the phased approach framework. For example, in the ROP, PRAs are used in two ways. The first use is to focus the inspection program on safety significant issues. This can be done using generic risk insights and does not require a plant specific PRA. The second use is as the basis for the notebooks generated to support the significance determination process. This process provides inspectors with a tool to determine the potential risk significance of a finding, and is based on order of magnitude estimates. While the notebooks are based on the structure of the licensees' PRAs, they are not intended to be detailed models, but are intended to provide order of magnitude estimates of risk significance. In this context, it may not be necessary to classify this use of PRA as a Phase 1 or a Phase 2 application. However, if a licensee were to challenge an assessment of the risk significance by using its own PRA model (Phase 3 of the SDP process), the quality of the licensee's PRA model could play a significant role.

This is a key task, and the description of this task will be expanded in the final plan.

3.1.3 Task 3: Identify the Staff Activities for Developing the Guidance Documents

The objective of this task is to identify specific activities related to the development of the guidance documents identified in Task 2. Staff activities are currently in place which will provide many of the necessary guidance documents. While the activities all require coordination between NRR and RES, one office has the lead for each specific activity. These activities and the associated leads include:

- Supporting professional standards organizations in developing PRA standards (RES/NRR)
- Developing and issuing regulatory guidance on staff positions on professional standards (RES)
- Developing other supporting document(s)/NUREG on guidance for specific PRA and related issues; e.g.,
  - treatment of uncertainties (RES)
  - acceptability of alternate methods (RES)
- Developing application specific regulatory guides including addressing PRA quality (RES)
- Developing methods to address technical issues as needed to support PRA quality (RES)
- Implementation of the different risk-informed activities:
  - tech specs (NRR)
  - RG 1.200 pilots (NRR)
  - 50.69 (NRR)
  - 50.46 (NRR)

- ROP (NRR)
- others (NRR)

3.1.4 Task 4: Define the Schedule for Each Application Type for Achieving Phase 2

This task will define a schedule for developing the guidance necessary to transition to Phase 2 as a function of the application type. This schedule will of necessity be conditioned on the completion of the necessary standards documents. The current schedule is presented in Table 3.1 below.

Table 3.1 Schedule for Completion of Standards and NRC Endorsement

PRA Standard	Std's Org	Anticipated Completion Date	Anticipated NRC Endorsement
External Events	ANS	Completed	December 2004
Low Power and Shutdown Mode	ANS	2005	2006
Internal Fires	ANS	2005	2006

This table does not include other scope items (e.g., Level 2 and Level 3 PRA) that may be considered necessary for certain applications. The schedule for implementation of the plan will be modified if and when such items are determined to be necessary.

The transition to Phase 2 will be different for applications depending on the scope of PRA essential to the decision being made. Using the proposed rule 50.69 as an example, the industry guidance is such that the scope of application is limited to only those SSCs that can be classified using a PRA model, and that are not relied on to maintain low risk for those risk contributors that are not analyzed using a PRA model. Thus, within the Phase 2 framework, the scope of potential SSCs can grow with time as the Standards are finalized and reviewed, as illustrated in Table 3.2 and Figure 3.1.

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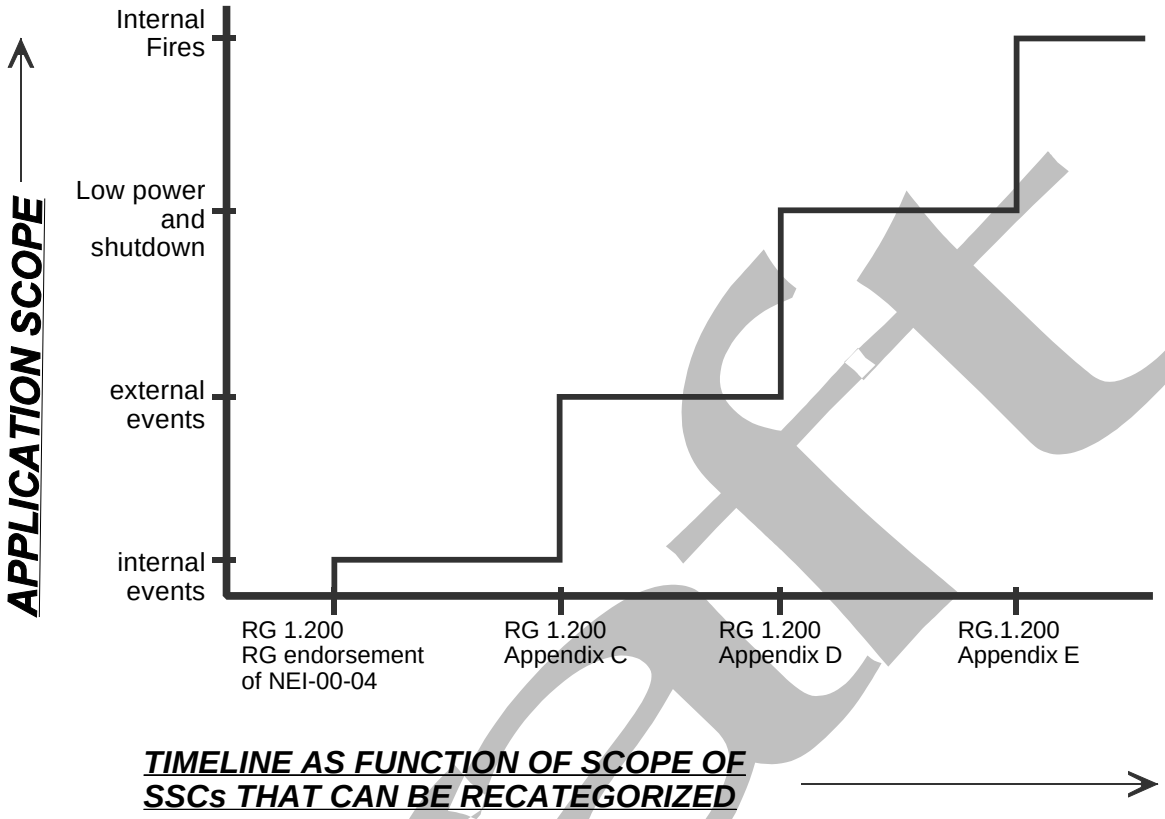

Figure 3.1

Table 3.2 Scope of SSCs recategorized for Phase 2 as a function of completion of PRA Standards

Scope of SSCs recategorized	When scope can be achieved
Those addressed in Internal Events PRA only	On completion of Reg Guide endorsing NEI-00-04
Those addressed in Internal Events PRA and External Events PRA	On completion of Appendix C of RG 1.200
Those addressed in Internal Events PRA, External Events PRA, and Low Power and Shutdown PRA	On completion of Appendix D of RG 1.200
Those addressed in Internal Events PRA, External Events PRA, Low Power and Shutdown PRA, and Internal Fires PRA	On completion of Appendix E of RG 1.200

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As noted above, the transition into Phase 2 will be different for applications depending on the scope of PRA essential to the decision being made; that is, to be in Phase 2, the licensee's base PRA needs to conform to the existing standards for the risk significant contributors associated with the application. A common understanding of what is meant by a risk significant contributor is needed. A definition at the level of accident sequences, cutsets, and basic events has been proposed by the staff in RG 1.200 and will be tested during the trial period in the pilot applications. The extension of these definitions to a risk significant contributor[2] will be accomplished during this task.

3.1.5 Task 5: Develop Phase 3 Guidance

This task will develop the Phase 3 guidance document. The Phase 3 guidance document is currently thought of as being an umbrella document that represents the union of all the documents related to quality for the PRAs addressing contributors to risk that are significant to any of the envisioned applications.

3.1.6 Task 6: Develop Implementation Guidelines

The objective of this task is to develop guidelines and procedures for the implementation of the plan to achieve the objectives as outlined in Section 1.2 of this plan. This task includes the modification of staff process and guidance documents for the review and approval of risk-informed submittals, and the communication of the expectations with respect to PRA quality for those submittals to all stakeholders.

It is the Commission's expectation that, once the technical guidance is in place for an application to be treated as a Phase 2 application, and the implementation procedures are in place, if an application is received that does not conform with the Phase 2 guidance, it will be given low priority. The reason for this is primarily one of efficiency, since the staff review would be expected to be more resource intensive for a non-conforming submittal.

Those applications that remain in Phase 1 because the guidance is not complete for those contributions to risk that could significantly affect the decision, will be afforded the same level of priority they currently receive. However, there are applications where the scope of application is discretionary, e.g., 50.69. As described in section 3.1.4, the scope of SSCs in 50.69, as a Phase 2 application increases as the guidance documents for the various scope items are completed. If a licensee submits a 50.69 application before such guidance is completed, it is effectively a Phase 1 application and would be given low priority on the basis of efficiency of review. This would encourage the development of Standards, while it would in the short term limit those licensees who have more complete models prior to issuance of associated guidance documents. [This has been identified as a potential policy issue.]

Once the guidance is in place, there will be a phasing in of the expectations on submittals as illustrated in Table 3.3.

[2] In this context a significant contributor is an operational mode or initiating event type that could change a decision substantially

Table 3.3 Milestones

MILESTONE	**PROJECTED COMPLETION DATE**
Identify Current Risk-Informed Applications (e.g., 50.69)	July 30, 2004
Identify PRA Quality Needs for Each Risk-Informed Application	December 30,
Revise Application-Specific Guidance to Address PRA Quality	December 30,
PRA Quality (RG 1.200) Pilots for Internal Events	December 30,
Implementation - Quality for Internal Events PRA (Note 1)	September 30,
Alternate Methods & Treatment of Uncertainties NUREG	December 30,
Standards Development - ANS External Events PRA Quality	*Completed*
NRC Endorsement - ANS External Events Standard	December 30,
Implementation - Quality for External Events PRAs (Note 1)	December 30,
Standards Development - ANS Fire PRA Quality	June 30, 2005
NRC Endorsement - ANS Fire PRA Standard	June 30, 2006
Implementation - Quality for Fire PRAs (Note 1)	June 30, 2007
Standards Development - ANS Low Power & Shutdown PRA Quality	June 30, 2005
NRC Endorsement - ANS Low Power & Shutdown Standard	June 30, 2006
Implementation - Quality for Low Power & Shutdown PRAs Standard	June 30, 2007
Develop Phase 3 Guidance	

Note 1: For the purposes of this draft, it is assumed that the Standards documents will lag the guidance documents for the applications. It is further assumed that a delay of one year between the completion of the quality guidance documents and that time at which each application is expected to conform to those documents is sufficient for the review of the associated PRA elements to be completed. Furthermore, this time delay allows for the staff infrastructure necessary to transition to Phase 2 to be developed.

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3.1.7 Task 7: Continued Ad Hoc Monitoring of PRA Quality

The objective of this task, which is an ongoing task, is to use opportunities provided by the risk-informed license application reviews, exercising Phase 3 of the significance determination process, and any benchmarking of NRC models (SPAR, SDP notebooks) to give insights into the technical adequacy of licensee PRAs. In Phase 1, this will be an extension of the current practices, but with a more formal approach to the documentation and dissemination of lessons learned. In Phase 2, there should be less of a need for ad hoc reviews, since the Standards will be in place to assess the technical adequacy of the baseline PRAs used to support the applications. However, it is the staff's intent to perform limited audits of the PRAs as part of application reviews. This may or may not use the SPAR models as a sanity check on the results of the licensees' PRAs to highlight potential issues.

3.2 Resolution of Technical Issues

The SRM directs the staff to discuss the resolution of technical issues. The three issues specifically called out in the SRM are discussed below. While implementing the plan, other technical issues requiring resolution may emerge. These will be addressed as necessary.

3.2.1 Model Uncertainty

An understanding of the relevant uncertainties is an essential element of risk characterization. This understanding should include a systematic treatment involving rigorous analyses for parametric uncertainties, and sensitivity studies to identify and quantify the model uncertainties. However, sensitivity studies should be used to identify what is important to the results and not to replace uncertainty analyses. Further, the ASME PRA standard requires that *"Uncertainties in the PRA results shall be characterized. Key sources of model uncertainty and key assumptions shall be identified, and their potential impact on the results understood."* The standard allows this requirement, regarding model uncertainties, to be accomplished by performing sensitivity studies. In addition, in RG 1.174, the approach outlined consists of identifying the principal sources of uncertainty and testing the decision against those uncertainties using sensitivity studies. There is little to no guidance on what constitutes an acceptable sensitivity analysis, nor is there any guidance on how to factor the information into the decision making process. RES has initiated an effort to provide guidance on acceptable sensitivity analyses and guidance on the treatment of uncertainties in decision making. This guidance will be published in a NUREG report.

3.2.2 Treatment of Seismic and Other External Events

The American Nuclear Society has just published an "American National Standard External-Events PRA Methodology" (December 2003). This standard sets forth requirements for external-event PRAs used to support risk-informed decisions for commercial nuclear power plants and to prescribe a method for applying the requirements for specific applications. The external events covered by the standard include both natural external events (e.g., earthquakes, high winds, and external flooding) and human-made external events (e.g., airplane crashes, explosions at nearby industrial facilities, and impacts from nearby transportation activities). The staff is reviewing this standard and plans to provide its position in Appendix C to RG 1.200. This standard, as in the ASME PRA standard for a Level 1 and limited Level 2 PRA, and as in RG 1.174, if the scope of

either the PRA or the standard is insufficient, supplementary analyses (e.g. bounding analyses, sensitivity) may be used. Further, as noted above, there is little to no guidance on what constitutes an acceptable bounding analysis or sensitivity analysis, nor is there any guidance on how to factor the information into the decision making process. RES has initiated an effort to provide guidance on acceptable sensitivity analyses and guidance on the treatment of uncertainties in decision making. In addition, this effort will identify the characteristics of an acceptable bounding analysis. This guidance will be published in a NUREG report.

To some extent this will resolve itself in time as the standards are developed. However, there is an issue that needs to be addressed, and that is when is a contributor significant enough to warrant being addressed by the performance of a PRA. Related to this is the RES program which will define what is an appropriate method for defining the characteristics of a bounding that make it sufficient to draw the conclusion that the contribution is insignificant.

3.2.3 Human Performance Issues

Human performance issues are dealt with in PRAs by the performance of a Human Reliability Analysis (HRA). The impact of human performance on risk is modeled through the inclusion of human failure events (HFEs) in the event trees and fault trees, and the estimation of the probabilities, called human error probabilities (HEPs) for those events. There are several approaches to evaluating HEPs, and there is considerable variability in the estimation of HEPs. RES has developed an HRA research program addressing HRA quality issues. A primary activity of this program is the development of HRA guidance which, when implemented, will improve HRA practices. It includes the development of HRA good practices and the review and evaluation of existing HRA methods for their capability to meet the "good practices" for different HRA applications. The HRA guidance will address many potential weaknesses associated with HRA, including the ability of an individual HRA method to support different regulatory applications, the lack of consistency among HRA practitioners on implementing HRA methods, and the absence of guidance on the necessary rigor needed for quantification of human reliability.

RES is also developing a database entitled Human Event Repository and Analyses (HERA) to support both human factors and HRA applications. It encompasses the development of a database structure and the collection of information from operational events or other sources suitable for HRA. Such a repository will mark a significant step towards addressing the issue of quality of data for HRA, viewed by practitioners as a significant limitation of HRA state-of-the art.

One of the emerging issues is likely to be the assessment of human performance during the low power and shutdown modes of operation, since there are fewer automatic system responses to initiating events, and there is an increasing reliance on operator response.

4.0 RESOURCES

(Later)

5.0 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, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.174, Revision 1, November 2002.[3]

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

4. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," Regulatory Guide 1.175, August 1998.[1]

5. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping," Regulatory Guide 1.178, Revision 1, September 2003.[1]

6. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," Regulatory Guide 1.176, August 1998.[1]

7. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," Regulatory Guide 1.177, August 1998.[1]

8. Nuclear Energy Institute, "Probabilistic Risk Assessment Peer Review Process Guidance," NEI-00-02, Revision A3, March 20, 2000.[4]

9. USNRC, SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," October 29, 1999.[5]

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[3] Requests for single copies of draft or active regulatory guides (which may be reproduced) and certain SRP sections, or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301)415-2289; email <DISTRIBUTION@NRC.GOV>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.

[4] Copies may be obtained from the Nuclear Energy Institute, Attn: Mr. Biff Bradley, Suite 400, 1776 I Street, NW, Washington, DC 20006-3708; phone (202)739-8083.

[5] Copies are available electronically through NRC's web site, <www.nrc.gov> through the Electronic Reading Room to Commission Documents. Copies are also available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike (first floor), Rockville, MD; the PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301)415-4737 or 1-(800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>.

10. Letter from NEI, Anthony Pietrangelo, Director of Risk and Performance Based Regulation Nuclear Generation, to the USNRC, Ashok Thadani, Director of Office of Nuclear Regulatory Research, December 18, 2001.

11. American Society of Mechanical Engineers, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," ASME RA-S-2002, April 5, 2002, and "Addenda to ASME RA-S-2002," ASME RA-Sa-2003, December 5, 2003. [6]

12. American Nuclear Society, "American National Standard External-Events PRA Methodology", ANSI/ANS-58.21-2003

13. USNRC, "Proposed Rulemaking to Add New Section 10 CFR 50.69, 'Risk-Informed Categorization and Treatment of Structures, Systems, and Components' WITS 199900061," SECY-02-0176, September 30, 2002.[5]

14. USNRC, ""Staff requirements - SECY-02-0057 - Update to SECY-01-0133, March 31, 2003

15. USNRC, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities", Regulatory Guide 1.200, for trial use, February 2004

16. USNRC, COMNJD-03-0002 "Stabilizing the PRA Quality Expectations and Requirements"

[6] Copies may be obtained from the American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990; phone (212)591-8500.