POLICY ISSUE
(Notation Vote)

July 13, 2004 SECY-04-0118

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: PLAN FOR THE IMPLEMENTATION OF THE COMMISSION'S PHASED APPROACH TO PROBABILISTIC RISK ASSESSMENT QUALITY

PURPOSE:

To provide the Commission with the action plan for the implementation of the phased approach to probabilistic risk assessment (PRA) quality, and to inform them of anticipated staff resource impacts.

To request Commission direction and additional guidance on policy issues related to the implementation of the plan.

BACKGROUND:

On December 18, 2003, the Commission issued Staff Requirements Memorandum (SRM) COMNJD-03-0002, "PRA Quality Expectations and Requirements." In the SRM, the Commission approved implementation of a phased approach to achieving an appropriate quality for PRAs for Nuclear Regulatory Commission's (NRC) risk-informed regulatory decisionmaking. This phased approach was described in an attachment to the SRM. The SRM directed the staff to develop an action plan that would define a practical strategy for the implementation of the phased approach to PRA quality. In addition, the SRM directed the staff to discuss the resolution of technical issues, such as model uncertainty, treatment of seismic and other external events, and human performance issues.

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DISCUSSION:

The plan was developed jointly by the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Regulatory Research (RES). Drafts of the plan were distributed to stakeholders internal to the NRC, and were made available on the NRC public web site for external stakeholders. The staff held public meetings on the draft plan on February 24, March 24 and May 13, 2004. The staff met with the Advisory Committee on Reactor Safeguards (ACRS) subcommittee on PRA on March 25, 2004, and with the full committee on April 15, 2004. The ACRS issued a letter on April 27, 2004, broadly supporting the plan, with some additional recommendations. Letters have also been received from the Nuclear Energy Institute, the American Society of Mechanical Engineers (ASME) and the American Nuclear Society, the Westinghouse Owners Group, and the Electric Power Research Institute. These stakeholders expressed their general support for the staff's plan. This final version of the plan considers the input received from these stakeholders.

The term PRA quality has been interpreted in different ways by different stakeholders, resulting in some confusion and misunderstanding. In this plan, PRA quality is defined as in Regulatory Guide (RG) 1.174 and RG 1.200 as having three aspects: the scope of risk contributors addressed (full power, low power and shutdown modes of operation, internal initiating events, and external initiating events), the level of detail, and the technical adequacy of the model. Inherent in this definition is that a PRA of sufficient quality to support an application need only have the scope and level of detail sufficient to support that application, but it must always be technically adequate.

The plan covers the first three phases defined in the SRM, and identifies the activities required to support implementation. As directed by the SRM, the feasibility of the fourth phase will be assessed following achievement of Phase 3. The phases are achieved for specific risk-informed activities when guidance documents are available to support those activities, and in particular to address the issue of the quality of PRA necessary to support the activities. Phase 1 represents the current situation, where guidance on PRA quality is general, and staff review of the base PRA supporting the activity is performed on a case-by-case basis. Phase 2 takes advantage of the work that has been performed to develop PRA standards. Phase 2 occurs when there are PRA standards and the associated regulatory guides in place to address those PRA scope items that are significant to the decision. To be in Phase 2 for an application, the licensee's submittal is expected to be in conformance with the published standards. The PRA standards are being developed on different schedules. As a result, the risk-informed activities will transition to Phase 2 on different schedules according to which scope items are significant to the decision. Table 3.3 of the plan provides the schedule for implementation of Phase 2 as a function of PRA scope. Phase 3 provides a regulatory framework for the development of a PRA that will be of sufficient quality to support all current and anticipated applications. Phase 3 will be completed by December 31, 2008.

In implementing the phased approach, the plan calls for specific application types to be defined, and the necessary guidance documents identified. Additional guidance documents will be developed on a schedule that is a function of when the standards are developed. The implementation schedule has a built-in grace period to allow licensees to implement the new guidance. To implement the phased approach, a process will be developed for prioritizing and scheduling submittal reviews. This prioritization process is necessary to balance the need to use staff resources effectively and efficiently and the need to provide incentives for licensees to

develop more complete PRA models. Because the development of the guidance documents will be achieved over an extended time, the staff intends to continue to use other opportunities (e.g., review of licensee submittals, review of licensee Phase 3 Significance Determination Process (SDP) evaluations, Accident Sequence Precursor Analyses) to monitor the scope, level of detail, and technical adequacy of licensee PRAs. The staff plans on working closely with industry in the development of the guidance documents, and will develop the necessary standards not developed by a Standards Developing Organization (e.g., ASME).

In addition to providing a strategy for the implementation of the phased approach, the plan addresses the identification and resolution of technical issues (e.g., model uncertainty, the treatment of seismic and other external events, and human performance). It should be noted that the specific activities identified in the SRM are already under way. However, it is likely that, as the guidance is implemented, additional technical issues requiring resolution will be identified. In addition, it is the staff's intention to use the Standardized Plant Analysis Risk (SPAR) models to assist in identifying any additional technical issues and in prioritizing their resolution.

As part of the implementation of the plan, the staff will develop a communications plan. The objectives of this plan are to: (1) explain the staff activities to stakeholders, (2) describe the staff's approach, and (3) provide a structure for communicating the messages to stakeholders.

The action plan will be revised as necessary if schedules for the development of guidance documents change.

IMPLEMENTATION ISSUES:

A key to the successful implementation of the phased approach is the development of a process for the prioritization and scheduling of the staff's review of risk-informed submittals. This process is intended to establish a balance between the need to use staff resources effectively and efficiently and the provision of incentives for licensees to develop more complete PRAs. The attachment to the SRM states that, once Phase 2 has been reached, the staff should give low priority to, or return, nonconforming applications because of their adverse effect on effectiveness and efficiency. Following discussion with stakeholders, the staff has included, as one of the first tasks in the plan, the development of a process for the scheduling and prioritization of reviews of licensee submittals, taking into account such issues as the following:

- whether the staff resources required to review the PRA results for those significant scope items not addressed by the use of standards are available
- whether the application has a safety benefit
- whether there is a potential benefit to the licensee (economic, needed for outage planning, etc.)
- whether the application furthers the state of practice
- whether the application is a pilot for an application that is seen as having a net safety benefit

In determining how the phased approach would be implemented, two policy issues were identified:

Policy Issue 1 —
Issue:

Phase 2 occurs when there are available PRA standards and regulatory guidance to address the PRA scope items that are significant for a specific application. Phase 3 occurs when there are available PRA standards and regulatory guidance to address all current and anticipated applications. Although PRA standards and regulatory guidance for all current and anticipated applications may be available (Phase 3), the licensee may choose not to upgrade their PRA to support all such applications. The licensee may decide on a risk-informed activity that does not utilize all the available PRA standards and regulatory guidance. The staff believes this decision is acceptable. Consequently, every licensee would not be required to update their PRA to all available guidance completely before participating in risk-informed activities.

Pros:

- Licensees interested in only one or two applications would not have to develop a Phase 3 PRA conforming to all the available PRA standards and regulatory guidance.
- For licensees only interested in simple, same-type applications, requiring a Phase 3 PRA could serve as a disincentive to the licensee.
- Efficiencies in staff review would occur for licensees only submitting simple, same-type applications[1].
- Reduction of unnecessary burden for some licensees.

Cons:

- If there is no requirement for a Phase 3 PRA, there may be little incentive for development of a Phase 3 PRA. That is, licensees may not take advantage of the added benefits such as analyzing events and performing SDP evaluations.
- Inefficiencies in staff review would occur if licensee submits multiple, more complex applications.

Recommendation:

Phase 2 applications are acceptable even after Phase 3 guidance is in place.

Policy Issue 2 —
Issue:

[1]Examples of simple, same-type applications include inservice inspections and allowed outage time extensions for accumulators.

Phase 1 represents the current situation: PRA standards and regulatory guidance are incomplete. Phase 2 and Phase 3, as noted above, occurs when (1) there are PRA standards and regulatory guidance to address the PRA scope items that are significant for a specific application, and (2) there are PRA standards and regulatory guidance to address all current and anticipated applications, respectively. Although PRA standards and regulatory guidance for all current and anticipated applications may be available (Phase 3), the licensee may again choose not to upgrade their PRA to support all such applications. The licensee may decide on an application even though their PRA is not supported by the available PRA standard and regulatory guidance for that specific application (Phase 2). The staff does not agree with this decision. The staff believes that a licensee's application, where the PRA does not conform to at least the Phase 2 guidance, should be rejected. Therefore, licensees would not be allowed to submit individual Phase 1 applications once Phase 3 guidance is in place.

Pros:

- Licensees would have an incentive to develop and use more complete PRAs.
- Efficiencies in staff reviews would occur; staff review would not be performed on a case-by-case basis.

Cons:

- Stakeholders may argue that not allowing use of alternate approaches (such as margin type analyses with compensatory measures) would result in an unnecessary burden for simple, well-understood applications that have an established history.
- By rejecting Phase 1 applications in the future, it could be misinterpreted that the current practice (Phase 1) was inadequate.

Recommendation:

Once Phase 3 guidance is in place, Phase 1 applications would no longer be accepted.

RESOURCES:
The resources in the NRR and RES budget for the tasks in the plan for FY2004 - FY2006 are listed in the table below. Resources for the tasks to be completed in FY2007 - FY2008 will be allocated consistent with the agency's Planning, Budgeting, and Performance Management (PBPM) process.

	FY04 $	FY04 FTE	FY05 $	FY05 FTE	FY06 $	FY06 FTE
NRR	0	0.6	0	1.3	0	0.8
RES	$700K	1.2	$750K	1.5	$775K	1.5
Total	**$700K**	**1.8**	**$750K**	**2.8**	**$775K**	**2.3**

RECOMMENDATIONS:

The staff recommends that the Commission approve the following:

- Phase 2 applications are acceptable even after Phase 3 guidance is in place.
- Once Phase 3 guidance is in place, Phase 1 applications would no longer be accepted.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

/RA/

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for Operations

Attachment: Action Plan: Stabilizing the PRA Quality Exceptions and Requirements

ACTION PLAN

STABILIZING THE PRA QUALITY EXPECTATIONS AND REQUIREMENTS

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1 Background

The Commission, by publishing its Final Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities (Ref. 1), reflected its belief 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. Furthermore, the Commission stated its belief 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 recognized, and encouraged, 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 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 the use of PRA information in the risk-informed reactor regulatory activities, and on PRA quality.

- 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. 2) 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. 3).

  On August 16, 2002, NEI submitted draft industry guidance for self-assessments (Ref. 4) to address the use of industry peer review results in demonstrating conformance with the American Society of Mechanical Engineers (ASME) PRA standard. This additional guidance, which is intended to be incorporated into a revision of NEI-00-02 (per NEI, see Reference 4), 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 ASME and the American Nuclear Society (ANS). On April 5, 2002, ASME issued a standard for a full-power, internal events (excluding internal fire but including internal floods) Level 1 PRA and a limited Level 2 PRA, supplemented by addenda on December 5, 2003 (Ref. 5). In December 2003 ANS issued a standard for external events (Ref.6), which addresses seismic, high wind, external flood, and other (e.g., aircraft crash, chemical release) hazards. 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.

- RG 1.200 (Ref. 7), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued for trial use. RG 1.200 is expected to provide the level of confidence that the technical adequacy of the PRA is sufficient 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 regulatory guide (RG) will allow staff members to focus their review on key assumptions and areas identified by peer reviewers as being of concern and 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 staff requirements memorandum (SRM) (Ref. 8) 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. The phased approach defines the needed PRA quality for current or anticipated applications and the process for achieving this quality, while allowing risk-informed decisions to be made using currently available methods until all 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 10 CFR 50.46 and 10 CFR 50.69 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 PRA 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 the quality of the baseline PRA needed to support current risk-informed reactor activities and the associated guidance documents supporting these activities. The plan does not address directly the modifications of the baseline PRA needed to support specific applications (referred to in the attachment to the SRM as one of the "risk-informed decision making elements"). These will be addressed in the specific guidance documents for those applications.

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- phase approach to PRA quality that provides a pathway for the continued 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, for 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 (as defined in Section 2.1), level of detail, and technical adequacy.

Only the first three phases are addressed in this plan, as required by the SRM. The feasibility (including resource evaluation) for pursuing Phase 4 will be evaluated after Phase 2 and Phase 3 have been achieved.

In this chapter, Phases 1, 2, and 3 are defined, the activities needed to achieve each phase are identified, and the proposed effect the implementation of the phases will have on the staff review of risk-informed licensing submittals is described.

2.1 Definition of the Phases

In this section, Phases 1, 2, and 3 are defined. Each phase is characterized in terms of the available guidance documents relative to the risk-informed activities. What distinguishes the phases is the availability and implementation of technical guidance documents that address the use and quality of the PRA with scope and level of detail necessary to support an application.

In addition, another distinction between the phases is the type and extent of the staff review of risk-informed licensee submittals (see Section 2.3). Staff review will become more focused, and the staff's confidence in the use of the baseline PRA model to support an application will be greater when the PRA standards and guidance exist for the defined PRA scope for an application. When PRA standards or guidance do not exist for the defined PRA scope or application, the staff review to achieve the same level of confidence will of necessity be more resource intensive. It should be expected that those staff reviews that are more resource intensive will also take longer to complete and will likely be placed on an extended schedule (and have a different application-specific completion goal). Furthermore, if a licensee's base PRA does not conform to the existing endorsed PRA standards defined for the specific application for the risk-significant contributors, but addresses these contributors by other means (e.g., qualitative arguments or reliance on unquantified compensatory measures), a more extensive staff review will be implemented. An important task in this plan is to define a process with which to schedule and prioritize the reviews of submittals according to how they conform to existing guidance.

The PRA scope to support an application is defined in terms of the:

- Risk metric used in the decision (e.g., core damage frequency (CDF), large early release frequency (LERF), health effects)
- Coverage of initiating events (internal events, internal fires, and external events such as earthquakes and high winds)
- Plant operational modes affected by the application (full power, low power and shutdown, transition)

The technical guidance documents are primarily:

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

At this time, consensus standards are not available to address the complete PRA scope as defined above. Table 1 shows the current status for consensus standards, and Table 2 lists some existing application specific and supporting guidance documents.

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 and endorsed in RG 1.200
	Level 2 (full)	TBD	development under consideration
	Level 3	TBD	development under consideration
Operating Modes	full power	ASME	available for Level 1 and LERF
	low power and shutdown	ANS	under development (projected draft in 2005)
Initiating Events	internal (transients, LOCAs, floods)	ASME	addressed for Level 1 and LERF in ASME standard
	internal (fires)	ANS	under development (projected draft in 2005)
	external (seismic, winds, floods, other)	ANS	published (Level 1 and LERF) under staff review

Table 2 Status of Guidance Documents

APPLICATION	DOCUMENT	ORIGINATOR	STATUS
License amendment	RG 1.174	NRC	Rev. 1
Inservice testing (IST)	RG 1.175	NRC	Rev. 0
Graded QA	RG 1.176	NRC	Rev. 0
Technical specifications	RG 1.177	NRC	Rev. 0
Inservice inspection (ISI) of piping	RG 1.178	NRC	Rev. 1
Technical adequacy of PRA	RG 1.200	NRC	issued for trial use, Rev. 0 projected March 2005
Endorsement of NEI-00-04	DG 1121	NRC	Draft, to be issued as RG 1.201 (expected Sep 2004)
Guidance for categorization of structures, systems and components (SSCs) by risk-significance	NEI-00-04	NEI	Rev. D

PRA peer review process	NEI-00-02	NEI	Projected completion TBD

The guidance documents in Table 2 will need to be revised to implement the phased approach as discussed in Section 3. To implement the guidance documents, some changes to NRC processes (e.g., license amendment review and metrics) 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 decisionmaking. Guidance for using PRA in regulatory decisionmaking exists in the form of regulatory guides such as RG 1.174, 1.175, 1.176, 1.177, and 1.178. These guides address PRA quality in a general way, stating that the quality of the PRA must be "commensurate with the application for which it is intended and the role the PRA results play in the integrated decision process." They do not, however, provide detailed guidance on what is technically adequate for the defined scope. The review of the base PRA used to support applications has been based on the reviewers' experience guided by previous staff reviews such as those performed on the Individual Plant Examinations (IPE) submittals, and on observations from peer reviews that were performed for the licensee. However, until recently (see below) there has been no formal guidance on PRA technical adequacy. The focus of the reviews has, in general, been 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 to those aspects of the licensee's PRA that have been identified as potential concerns in previous reviews.

In the past few years, progress has been made on clarifying the expectations on the technical adequacy of PRAs. These include:

- ASME RA-S-2002, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," issued in April 2002 (and Addenda ASME RA-Sa-2003, 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 (specifically 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.

As standards are developed and endorsed, it is expected that they will be used to address PRA quality for an application.

In this current phase, while all contributions to risk from the different operational modes and internal and external initiating events have to be addressed when making the decision, if the PRA does not include an assessment of some of these contributions, they may be addressed qualitatively, by bounding methods, by implementing compensatory measures, or by defining the change so that the risk from these missing contributions is not changed (i.e., does not significantly affect the decision).

Reviews of those changes to the PRA model to assess the impact of the proposed application are performed based on the application-specific guidance documents.

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 Inservice Inspection (ISI) applications, risk-informed technical specifications applications, and 10 CFR 50.69 applications), the baseline PRA that supports the application meets 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 whether the level of detail and technical adequacy of the PRA models for the significant modes of operation and initiating events (i.e., those whose inclusion could change the regulatory decision substantially) is sufficient to support the application.

In Phase 2 the staff review of the base PRA is performed in a more efficient way by virtue of a peer review of those parts of the baseline PRA necessary to support the application having been performed in accordance with RG 1.200. The staff review of the baseline PRA is focused on those parts of the PRA which the peer review has identified as not having been performed in accordance with the appropriate standard, and that are significant to the application, and on those key assumptions and sources of model uncertainty that are significant to the decision. Thus, the review is performed in a more formal and systematic manner.

Reviews of those changes to the PRA model in order to assess the impact of the proposed application are, as in Phase 1, performed based on the application-specific guidance documents.

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 the operational modes and initiating events that could affect a decision for existing and planned risk-informed applications. Therefore, to transition to Phase 3, a licensee will need a PRA that is of sufficient scope (in terms of operational modes and initiating events) to address currently envisioned applications and will meet the requirements of the applicable industry consensus standards.

As in Phase 2, in Phase 3 the staff review of the base PRA is more efficient by virtue of a peer review having been performed in accordance with RG 1.200. The staff review of the base PRA is focused on those parts of the PRA that the peer review has identified as not having been performed in accordance with the appropriate standard, and that are significant to the application, and on those key assumptions and sources of model uncertainty that are significant to the decision. In addition, a one-time staff review of the licensee's base PRA can be performed, instead of application-specific reviews.

2.2 Guidance Documents for 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. As noted above, these guidance documents include:

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

- PRA consensus standards
- regulatory guides and associated standard review plan chapters
- industry PRA application guides
- NRC- and industry-generated PRA reference documents (e.g., NUREGs, Electric Power Research Institute (EPRI) technical documents)

The PRA consensus standards provide the requirements for a technically adequate baseline 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 technical documents that provide guidance on how to perform the analyses and define the application-specific PRA scope. These documents are either in the form of regulatory guides (and associated standard review plans) or, in some cases, industry-developed application-specific guides. The industry-developed documents are endorsed in application-specific regulatory guides.

PRA reference documents provide detailed methods or guidance for specific aspects of the analysis.

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

- an application-specific regulatory guide, or industry guidance document endorsed by a regulatory guide, that specifies the quality of the PRA in terms of its scope, level of detail, and technical adequacy
- a standard for performing the PRA for each significant operating mode and initiating event type (i.e., internal, external, internal fires)[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. The pace at which the staff can achieve Phase 2 is, therefore, impacted to a large extent by development of the necessary standards by the Standards Development Organizations (SDOs) (e.g., ASME, ANS, ANSI).

For some application types, for example, risk-informed ISI, the associated RGs already exist, but they do not address the application-specific PRA quality needs other than in a very general sense. 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, will be endorsed in RG 1.201) or by the staff in the form of regulatory guides and standard review plan chapters.

For Phase 3, the staff will develop the necessary guidance to determine that the quality of a PRA is sufficient to support all current and anticipated applications. For a licensee to achieve Phase

[2]A significant operational mode or initiating event is one whose consideration could change the regulatory decision substantially.

3, the PRA must have been developed and a peer review performed using those quality standards as a basis.

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 Processing of Licensee Submittals

The processing of licensee submittals during and after the implementation of 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 that will be taken before the Phase 3 guidance is in place. Figure 2-2 shows the approach to be taken once the Phase 3 guidance is in place.

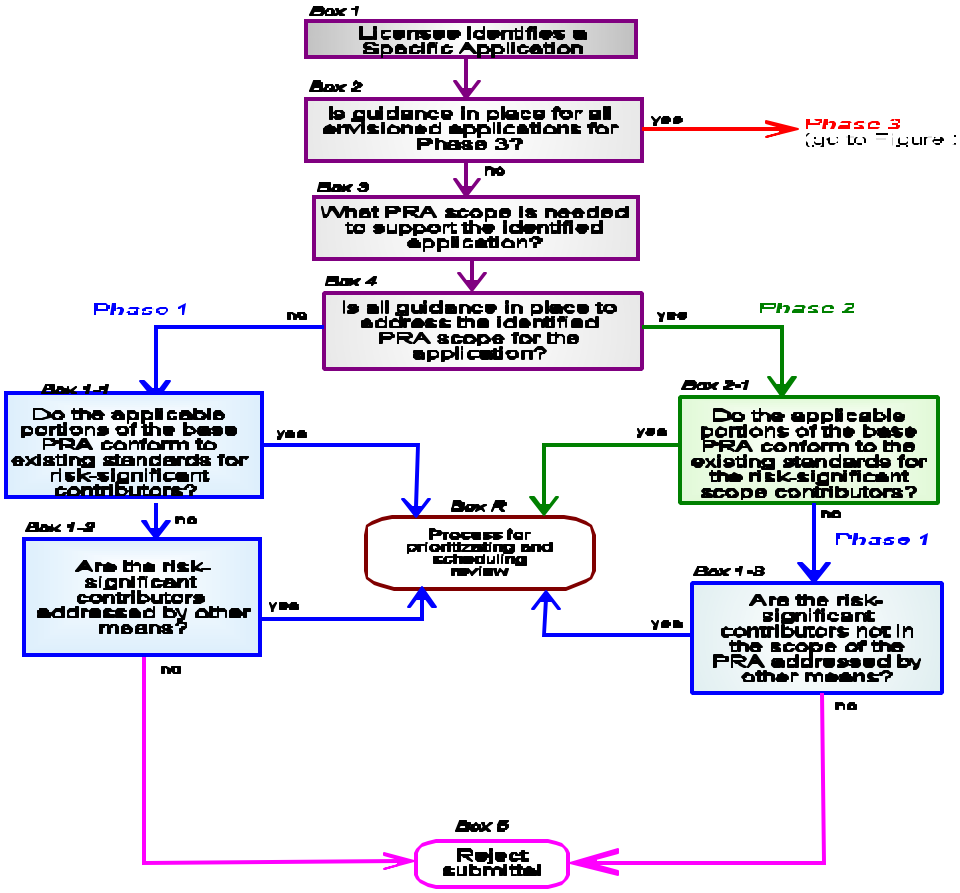


Figure 2-1 Review Process Before Phase 3

As shown on Figure 2-1, Box 2, once all the guidance documents are available for all envisioned applications, Phase 3 can be implemented (go to Figure 2-2). However, until all the guidance documents become available, a given application will either be in Phase 1 or in

Phase 2. Because different regulatory decisions may require a different scope of PRA, they will transition from Phase 1 to Phase 2 at different times, as discussed in Section 2.2. 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 perform the analysis to support the application and to address the technical adequacy of the PRA models for all significant modes and initiating events (see Footnote 2) 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 Phase 2 application on completion of the regulatory guide for performing the application, since a PRA standard exists for internal events and has been endorsed in RG 1.200. 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.

For an application classified as being in Phase 2, it is expected that the licensee's base PRA conforms to the applicable standards for the risk-significant modes and initiating events (Box 2-1, Figure 2-1). For the Phase 2 applications (Yes branch of Box 4, Figure 2-1), if the risk-significant modes and initiating events are included in the licensee's base PRA, then the application receives a Phase 2 staff review which is scheduled and prioritized based on a set of criteria to be developed by the staff (see Section 3.1.5) (Box R, Figure 2-1). These criteria are yet to be developed, but will be developed such that review of these applications would be expedited. The staff expects that these criteria will be published in a revision to the NRR office instruction on license amendment review procedures. The staff also expects that the guidance on tracking and reporting the status of license amendment reviews will have to be modified.

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. If the significant contributors are addressed by alternate means (Yes branch in Box 1-3, Figure 2-1), the application will be scheduled and prioritized in accordance with the criteria established by the staff (see Section 3.1.5). In the attachment to the SRM, the Commission suggested that such applications be given a low priority. If the significant contributors are not addressed by alternate means (No branch in Box 1-3, Figure 2-1), the submittal will be rejected as being inadequate (Box 5).

One subtlety associated with an application is that a licensee's submittal 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. This reduced scope submittal is possible 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 licensee's information 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 its review.

Phase 1 applications (No branch of Box 4, Figure 2-1) will initially be reviewed in the same manner as they are currently reviewed. As standards are developed and approved, however, it is expected that the licensee will use a PRA that conforms to those quality standards for those significant contributors for which guidance exists (Yes branch in Box 1-1), which will expedite the review process for the application. When existing standards are not used to assess the quality of the baseline PRA (No branch from Box 1-1), the submittal will enter the scheduling and prioritizing process if the risk significant contributors are addressed (Yes branch of Box 1-2), but

rejected otherwise (Box 5). The scheduling and prioritizing process will be constructed so that submittals conforming to existing standards will be given a higher priority than nonconforming submittals.

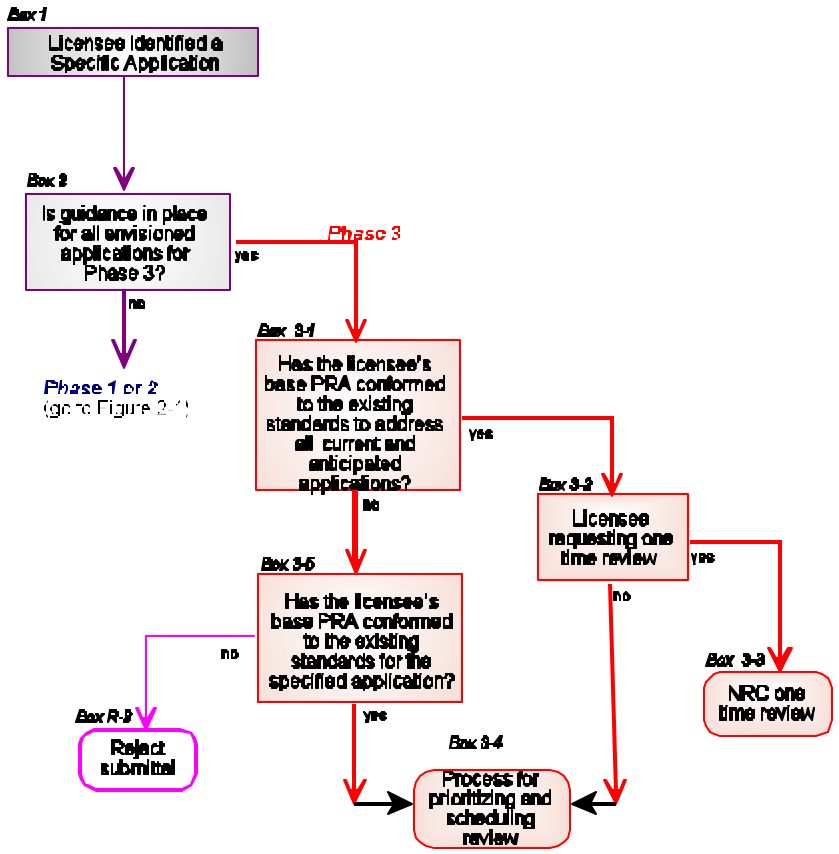
The scheduling and prioritizing process must also address an application in which a licensee uses a PRA which has a scope greater than the scope of the quality guidance that has been developed, with the purpose of expanding the scope of application to get increased relief from regulatory controls. An example is the use of a fire PRA in the implementation of 10 CFR 50.69 to expand the scope of SSCs that could be allocated to the RISC III category, prior to the development and endorsement of a fire PRA standard.

The scheduling and prioritization criteria will be established in Task 3.1.5. The issues that will be taken into account in developing the criteria and the associated process will include:

- the staff resources needed to perform the review (higher for those cases where standards are not developed and endorsed)
- the potential safety benefit of the application
- the potential benefit to the licensee (economic, schedule for plant modification, etc.)
- the degree to which the application enhances the state-of-practice or the state-of-the-art (e.g., a pilot application)
- the degree to which the comprehensiveness of the risk insights enhances the decision

Figure 2-2 applies when the Phase 3 guidance is complete. Once the guidance for current and anticipated applications has been published, a licensee can develop a PRA corresponding to Phase 3 quality (Box 2 of Figure 2-2). Once a PRA that meets all the quality requirements has been developed (Yes branch of Box 3-1), the licensee can request a “one time review” (Box 3-2). This staff review (and approval) will only be for application types included in the set defining Phase 3. At this point, a licensee could prepare documentation, independent of the application, assessing the quality of its PRA, which could be referenced in all future applications.

Figure 2-2
Review
Process
After
Phase 3



If a licensee chooses not to develop a full Phase 3 PRA (No branch in Box 3-1), then as long as the PRA meets the Phase 2 guidance for a specific application (Yes branch in Box 3-5), then that application will be given a Phase 2 review. However, if this is not the case (no branch in Box 3-5), the submittal will be rejected. This reflects a difference from Box 1-1 on Figure 2-1 and represents the increased expectation concerning the quality of the base PRAs in transitioning to Phase 3.

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

Throughout Phases 1, 2, and 3, the staff will continue to use opportunities provided by the risk-informed license application reviews, using Phase 3 of the Reactor Oversight Program (ROP) Significance Determination Process (SDP), Accident Sequence Precursor Analyses, and any benchmarking of NRC models (Standardized Plant Analysis Risk [SPAR], SDP notebooks) to gain insights into the technical adequacy of licensee PRAs.

3.0 APPROACH

This section identifies the staff activities to implement the Commission's directive. The first task is the development of 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.

The second task 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.

The third task is the development of a communications plan.

The office having the lead for each task is indicated in parenthesis. The plan will be updated periodically as required.

3.1 Task 1: Implementation of the Phased Approach

Implementation of the phased approach involves eight tasks:

- Task 1.1: Identification of Current Risk-Informed Applications
- Task 1.2: Specification of the Risk-Informed Application PRA Needs
- Task 1.3: Phase 2 Guidance Document Schedule
- Task 1.4: Development of Guidance Documents
- Task 1.5: Development of Prioritization Process for Staff Review
- Task 1.6: Phase 2 Implementation Schedule
- Task 1.7: Development of Phase 3 Guidance
- Task 1.8: Monitoring of PRA Quality

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

3.1.1 Task 1.1: Identification of Current Risk-Informed Applications (NRR)

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 may be grouped into one of four categories.

- Operational uses (e.g., use by a licensee to support the maintenance rule)
- Use of PRA in the ROP (e.g., SDP notebooks, licensee use of its PRA in Phase 3 of the SDP)
- License amendments (e.g., 50.69, risk-informed ISI)
- Implementation of new rules (e.g., 10 CFR 50.46)

The categories differ in the way in which PRA results are used to make decisions, and therefore the quality guidance may differ. For example, a licensee's use of a PRA to support implementation of the maintenance rule does not provide a change to or relief from the technical specifications in place at the plant, but supplements the regulatory framework. However, the use of a PRA in a license amendment may result in some relief from a regulatory requirement. The confidence needed in the PRA used to support these two applications is different. However, the improvement of the quality of the PRAs to support license amendments will have a beneficial effect on operational uses. For each of these categories, specific application types will be identified.

3.1.2 Task 1.2: Specification of the Risk-Informed Application PRA Needs (NRR)

The objective of this task is, for each application type, to specify, based on the role of PRA results in the application type, the scope and level of detail of the base PRA needed to support that role. Because of the way the decisionmaking 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 among applications, the capability of PRA in terms of these factors will also differ.

An important part of this task is to determine, for some applications, whether, and, if so, how the current approaches should change to be in conformance with the phased approach. One example of a licensee application is the maintenance rule in which risk information is used in a supplementary way to provide additional scrutiny on maintenance activities. Other examples include NRC-specific programs, such as the ROP, and the development and use of the SPAR models. For example, in the ROP, the notebooks generated to support the significance determination process are based on and benchmarked against the licensees' PRAs. This process provides inspectors with a tool to determine the potential risk significance of a finding, and is based on order of magnitude estimates. The notebooks are not intended to be detailed models, but are screening tools. In this context, while it may not be necessary to classify this use of PRA as a Phase 1 or a Phase 2 application, the notebooks are to some extent dependent on the quality of the licensees' PRAs. Furthermore, when a licensee uses its own PRA model to challenge an assessment of the risk significance (Phase 3 of the SDP process), the quality of the licensee's PRA model could play a significant role.

3.1.3 Task 1.3: Phase 2 Guidance Document Schedule (NRR)

This task will define a schedule for developing the guidance necessary to transition to Phase 2 for each application type. This schedule will of necessity be conditional 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	2006	2007

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 occur at different points in time for applications depending on the scope of PRA essential to the decision being made. Using the proposed 10 CFR 50.69 rule as an example, the industry guidance limits the scope of application to 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.

Table 3.2 Scope of SSCs Included in Phase 2

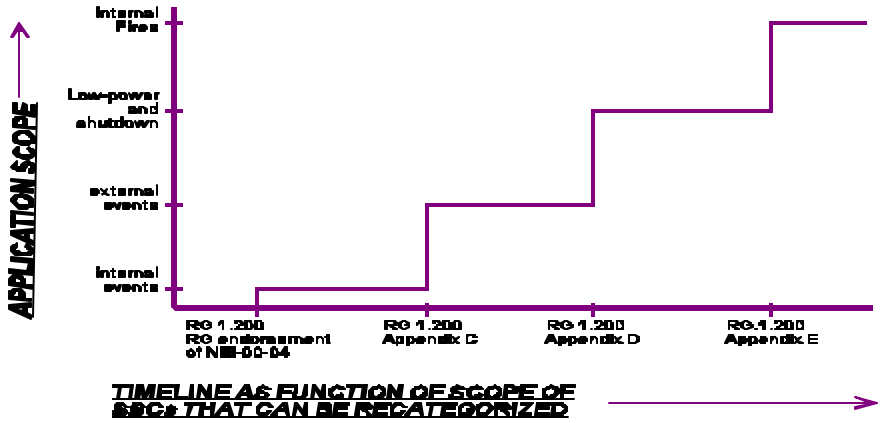
Scope of SSCs	When scope can be achieved
Those addressed in internal events PRA only	On completion of reg guide endorsing NEI-00-04
Those addressed in internal events PRA and external events PRA	On completion of Appendix C of RG 1.200
Those addressed in internal events PRA, external events PRA, and low-power 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

Figure 3.1

3.1.4 Task 1.4: Development of Guidance Documents (RES/NRR)

The objective of this task is to the develop the guidance documents identified in Task 2. This includes the development of the technical documents associated with the applications and the PRA quality aspects. In addition to the technical guidance documents, the task will also include 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. This will include clarification of what "trial use" of a document means in practice.

In developing these guidance documents, there will need to be a clear definition of what is a significant contributor at the level of a mode of operation or an initiating event. 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[3] (operating mode or initiating event) will be accomplished during this task. It should be noted that the Office of the Chief Financial Officer has approved fee waivers for five pilot applications of RG 1.200.

Staff activities are currently ongoing which when completed will provide many of the necessary guidance documents. While the activities all require coordination between NRR and RES, one office is assigned 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 documents/NUREGs on guidance for specific PRA and related issues; for example:
  - **S** treatment of uncertainties (RES)
  - **S** 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 for example:
  - **S** technical specifications (NRR)
  - **S** RG 1.200 pilots (NRR)
  - **S** 10 CFR 50.69 (NRR)
  - **S** 10 CFR 50.46 (NRR)
  - **S** ROP (NRR)

3.1.5 Task 1.5: Development of Prioritization Process for Staff Review (NRR)

It is the Commission's expectation that licensee submittals that conform to quality guidance that exists at the time of submittal be given a higher priority staff review than those that do not. The objective of this task is to establish a process for the prioritization and scheduling of the staff reviews that strikes a balance between the need to use staff resources effectively and efficiently and the provision of incentives to the licensees to develop more complete PRAs.

The issues addressed by this process will include the following:

- staff resources required to review the PRA results for those significant scope items not addressed by the use of standards (the impact of this on the prioritization and scheduling

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

will be different if standards exist and have not been used, or if they have not been developed and endorsed)
- the safety benefit of the application
- the potential benefit to the licensee (economic, schedule for plant modification, etc.)
- whether the application is furthering the state of practice
- whether the application is a pilot for an application that is seen as a net safety benefit

The process will be developed such that applications that are Phase 1 applications when the corresponding Phase 2 guidance is in place will receive a low priority, as recommended in the attachment to the SRM. However, since many such applications have already been processed and found acceptable, they would not be rejected outright.

One of the key issues that will be addressed is how to process an application in which a licensee uses a PRA which has a scope greater than the scope of the quality guidance in place to support the application, with the purpose of expanding the scope of application to get increased relief from regulatory controls. An example is the use of a fire PRA in the implementation of 10 CFR 50.69 to expand the scope of SSCs that could be allocated to the RISC III category. Not processing such an application would send the message that there is little benefit to be obtained by developing a more complete PRA, but on the other hand, reviewing such a submittal would require significantly more staff resources, which might take resources away from other, more straightforward, submittals.

For submittals, which are assessed to be low priority, new guidance and metrics need to be established concerning timeliness of review.

3.1.6 Task 1.6: Phase 2 Implementation Schedule (NRR)

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

Table 3.3 Milestones

Task	MILESTONE	**PROJECTED COMPLETION DATE**
1.1	Identify current risk-informed applications (e.g., 50.69)	August 31, 2004
1.2	Specify PRA quality needs for each risk-informed application	December 31, 2004
1.3	Phase 2 Guidance Document Schedule	December 31, 2004
1.4	Revise application-specific guidance to address PRA quality	December 31, 2005
	PRA quality (RG 1.200) pilots for internal events	December 31, 2004
	Implementation - quality for internal events PRA (Note 1)	September 30, 2005
	Standards development - ANS fire PRA	June 30, 2006
	NRC endorsement - ANS fire PRA standard	June 30, 2007
	Implementation - quality for fire PRAs (Note 1)	June 30, 2007
	Standards development - ANS low-power & shutdown PRA	June 30, 2005
	NRC endorsement - ANS low-power & shutdown standard	June 30, 2006
	Implementation - quality for low-power & shutdown PRAs	June 30, 2007
1.5	Development of Prioritization Process for Staff Review	December 31, 2004
1.6	Phase 2 Implementation Schedule	December 31, 2004
1.7	Develop Phase 3 guidance	December 31, 2008
1.8	Monitoring PRA quality	ongoing
2.1	Alternate methods & treatment of uncertainties, draft NUREG	December 31, 2004
2.2	Standards development - ANS external events PRA	*Completed*
	NRC endorsement - ANS external events standard	December 31, 2004
	Implementation - quality for external events PRAs (Note 1)	December 31, 2005
2.3	Human performance issues	Note 2

Note 1: For the purposes of this draft, it is assumed that the standards documents will lag behind 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.
Note 2: There are several activities, each with its own schedule and milestones.

3.1.7 Task 1.7: Development of Phase 3 Guidance (NRR)

This task will develop the Phase 3 guidance document. The Phase 3 guidance document is 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.

3.1.8 Task 1.8: Continued Monitoring of PRA Quality (NRR)

The objective of this task, which is an ongoing task, is to use opportunities provided by the risk-informed license application reviews, the exercising of Phase 3 of the significance determination process, and any benchmarking of NRC models (SPAR, SDP notebooks) to gain 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. The staff may or may not use the SPAR models to check the results of the licensees' PRAs in order to identify potential issues.

3.2 Task 2: Identification and Resolution of Technical Issues (RES/NRR)

The SRM directs the staff to discuss the resolution of technical issues. The three issues specifically called out in the SRM are discussed below. During the implementation of the plan, other technical issues requiring resolution may emerge. These will be addressed as necessary. That is, as the various guidance documents are developed, updated, and implemented, it is anticipated that additional technical issues will be identified that require a resolution. This task, therefore, goes beyond just resolution of the three issues identified by the Commission.

As each guidance document is developed, updated, or implemented, a systematic search for the key technical issues will be performed. For example, during the pilot of RG 1.200, the reviewers will identify any technical issues that appear to be addressed in a variety of different ways, such that they could affect the conclusions of an analysis. In addition, the staff intends to use the SPAR models to identify additional technical issues for which different technical approaches are used that have a significant impact on the results of PRAs. The SPAR models will be used to explore the sensitivity of the PRA results to these issues and provide input to prioritizing their resolution. For each issue identified, it will be determined if there is already an acceptable understanding and modeling of the issue. If not, a search will first be performed to determine if the issue is being addressed elsewhere. If the issue is being addressed, the schedule will be reviewed to ensure it supports the applicable guidance document. If the issue is not being addressed, either internally in a staff effort or externally in an industry effort, the issue will be evaluated in the prioritization process to determine how important it is that a resolution be found. If deemed important, then an activity will be implemented internally (or externally if industry elects to pursue the issue) and its schedule will be set, to the extent practical, to be in line with the applicable guidance document. This process is shown below in Figure 3.2.

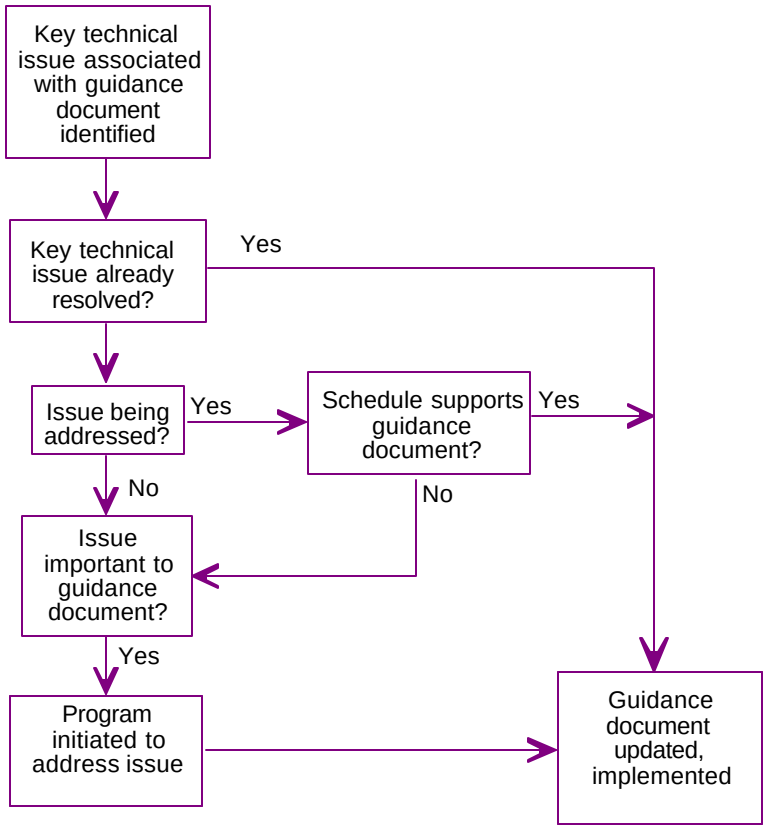


Figure 3.2 Process for assessing emergent technical issues

3.2.1 Task 2.1: Model Uncertainty (RES)

An understanding of the relevant uncertainties is an essential element of risk characterization. This understanding should include a systematic treatment, involving rigorous analyses of 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 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 or 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 Task 2.2: Treatment of Seismic and Other External Events (RES)

ANS has 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, states that, 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 guidance on what constitutes an acceptable bounding analysis or sensitivity analysis, nor is there any guidance on how to factor the information into the decisionmaking process. RES has initiated an effort to provide guidance on acceptable sensitivity analyses and guidance on the treatment of uncertainties in decisionmaking (see Section 3.2.1). 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 these issues will be resolved as the standards are developed. However, there is an issue that needs to be addressed, and that is when a contributor is significant enough to warrant being addressed by the performance of a PRA. The RES program on model uncertainty discussed in Section 3.2.1 will also address the definition of what is an appropriate method for defining the characteristics of a bounding analysis that make it sufficient to draw the conclusion that the contribution is insignificant.

3.2.3 Task 2.3: Human Performance Issues (RES)

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 in the event trees and fault trees, and through 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. The research program 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 in 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 in those operational modes, with an increasing reliance on operator response.

3.3 Task 3: Development of a Communication Plan

A communication plan will be developed. The objectives of this plan are to, (1) explain the staff activities to stakeholders, (2) describe the staff's approach, and (3) provide a structure for communicating the messages to stakeholders.

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

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

4. 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.

5. 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]

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

7. 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.

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

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[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.

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