

## PHASED APPROACH TO PRA QUALITY

TAC No. MC1747

Last Update: 07/30/07  
 Lead Division: DRA  
 Supporting Office: RES  
 CTL: N/A  
 GSI No.: N/A

TASK	MILESTONE	DATE (T/C)
1.1	Identify current risk-informed applications (e.g., 50.69)	03/31/04 (C)
1.2	Specify PRA quality needs for each risk-informed application	12/30/04 (C)
1.3	Phase 2 Guidance Document Schedule	12/31/04 (C)
1.4	Revise application-specific guidance to address PRA quality	12/31/08 (T)
	PRA quality (RG 1.200) pilots for internal events	02/28/05 (C)
	Standards Development - ASME internal events PRA, Addendum B	12/30/05 (C)
	Industry development - NEI peer review and self assessment process for internal events	05/19/06 (C)
	NRC endorsement - ASME and NEI internal events	01/31/07 (C)
	Implementation - quality for internal events PRA (Note 1) (Note 2)	1/01/08 (T)
	Standards development - integrated Level 1/LERF PRA (Note 3)	12/31/07 (T)
	NRC endorsement - integrated Level 1/LERF PRA (Note 3)	12/31/08 (T)
	Implementation - integrated Level 1/LERF PRA (Note 3)	12/31/09 (T)
	Standards development - ANS fire PRA	Being Balloted(T)
	Industry guidance - draft NEI internal fire PRA peer review	09/30/07 (T)
	NRC endorsement - ANS fire PRA standard and NEI internal fire peer review (Note 3)	12/31/08(T)
	Implementation - quality for fire PRAs (Note 1)	12/31/09(T)
	Standards development - ANS low-power & shutdown PRA Quality June 30, 2005	Under revision
	NRC endorsement - ANS low-power & shutdown standard (Note 3)	12/31/08(T)
	Implementation - quality for low-power & shutdown PRAs Standard (Note 1) June 30, 2007	12/31/09(T)
1.5	Development of Prioritization Process for Staff Review	12/30/05 (C)
1.6	Phase 2 Implementation Schedule	Note 4
1.7	Develop Phase 3 guidance	12/31/08 (T)
2.1	Treatment of uncertainties, draft NUREG -1855 for public comment (Note 5)	08/31/07(T)

TASK	MILESTONE	DATE (T/C)
2.2	Standards development - ANS external events PRA	rev.1 03/01/07(C),
	NRC endorsement - ANS external events standard (Note 3)	12/31/08(T)
	Implementation - quality for external events PRAs (Note 1)	12/31/09(T)

Note 1: It is 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: Regulatory Guide 1.200 Revision 1 was issued in January 2007. RIS-2007-06, documents the staff expectations with respect to the implementation of RG 1.200.

Note 3: The integrated standard combines the individual standards (i.e., internal events, internal fire, external events, low power and shutdown) into a single Level 1/LERF PRA standard. It is the staff's intent to endorse the internal fire, external events, and low power and shutdown PRA standards through the endorsement of the integrated ASME/ANS standard, rather than endorse the individual ANS standards.

Note 4: The schedule is dependent on the schedule for task 1.4. Based on informal feedback, the original proposal date of one year may be unrealistic given the resources available to perform the task.

Note 5: Primary lead organization is RES with input from NRR. It is the staff's intent to endorse the EPRI technical guidance documents on Treatment of Uncertainties in Risk-Informed Regulatory Applications in NUREG-1855.

Description: 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:

- a. Industry movement towards improved and more complete PRAs
- b. Increased efficiencies in the staff's review of risk-informed applications

- c. Clarification of expectations for 10 CFR 50.46 and 10 CFR 50.69 rulemakings
- d. 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.

There are three Phases 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.

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 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.

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 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 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.

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)

Revision 1 to NEI-00-02 was issued in November 2006.

- 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, and on December 30, 2005 (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. Revision 2 was issued on March 1, 2007. ANS plans to issue standards for PRAs for evaluating internal fire risk and risk from low-power and shutdown modes of operation before the end of 2007.

- RG 1.200 (Ref. 7), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," was 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.
- ANS and ASME have agreed to develop a PRA standard that will include all the constituent PRA standards in one document that will be issued as revision 1 to ASME -RA-S-2002.

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.

Proposed Actions: The milestones listed in the milestone table comprise the actions for this initiative. The only additional task was development of a communication 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. This communication plan was developed in the third quarter of the fiscal year 2005.

Originating Documents: None.

Regulatory Assessment: Not applicable.

Current Status: Regulatory Guide 1.200 Revision 1 was issued in January 2007. This revision provides the staff position on Addendum B to the ASME PRA standard and Revision 1 to NEI-00-02. RIS-2007-06, documents the staff expectations with respect to the implementation of RG 1.200.

Work has been completed on Task 1.5 (i.e., development of a prioritization process for staff review). The prioritization process is being incorporated into a revision of NRR Office Instruction LIC-101.

Task 1.6 provides for a phasing in of the expectations for submittals to allow licensees time to develop PRA models, and perform the necessary peer reviews or self assessments to demonstrate conformance with the appropriate standards, once those standards have been developed and endorsed by NRC. The schedule for this phasing in is dependent on the schedule in Task 1.4. Based on informal feedback received by the MSPI PRA quality task group and recent statements made by NEI at several meetings, the original proposal of one year for a delay in full implementation by the licensees, may be unrealistic given the resources available to perform these tasks. This will be revisited as more experience is obtained.

A draft NUREG-1855 entitled "Guidance on the Treatment of Uncertainties in Risk-Informed Decisionmaking", developed by RES, was issued for internal NRC staff review per the schedule (December 31, 2004). This has been reviewed by DRA staff and a revision to the document is planned for issuance for public comment in August 2007.

#### Contacts:

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#### 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. Revision 1 was issued on May 19, 2006, with additional clarification on November 15, 2006.
3. USNRC, SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," October 29, 1999.
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, "Addenda to ASME RA-S-2002," ASME RA-Sa-2003, December 5, 2003, and Addenda to ASME RA-Sb-2005, December 30, 2005.

6. American Nuclear Society, "American National Standard External-Events PRA Methodology," ANSI/ANS-58.21-2003, and Revision 1, ANSI/ANS-58.21.2007, March 1, 2007.
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."