



U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR REACTOR REGULATION

19.1 Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities

INTRODUCTION

In their March 1999 report, "Nuclear Regulation: Strategy Needed To Regulate Safety Using Information on Risk," GAO/RCED-99-95 (Ref. 1), the General Accounting Office (GAO) identified a number of issues that it believed required resolution for the NRC to successfully implement a risk-informed regulatory approach. Among these, GAO indicated that more was needed to "develop standards on the scope and detail of risk assessments needed for utilities to determine that changes to their plants' designs will not negatively affect safety."

Probabilistic risk assessment (PRA) standards have been developed by the American Society of Mechanical Engineers (ASME) and American Nuclear Society (ANS). On April 5, 2002, ASME issued a standard (Ref. 2) for a full-power, internal events (excluding fire) Level 1 and a limited Level 2 PRA. In the future, ANS plans to issue standards for PRAs for evaluating external events risk and risk from low power and shutdown modes of operation. In addition, reactor owners' groups have been developing and applying a PRA peer review program for several years, NEI-00-02, "Probabilistic Risk Assessment Peer Review Process Guidance," Revision A3 (Ref. 3). In a letter dated April 24, 2000, the Nuclear Energy Institute (NEI) submitted NEI-00-02 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. 4).

On December 18, 2001, NEI (Ref. 5) requested the staff to extend its review of NEI-00-02, and on August 16, 2002, NEI submitted draft industry guidance for self-assessments (Ref. 6) to address the use of industry peer review results in demonstrating conformance with the ASME PRA standard. This guidance supplements and will ultimately become part of NEI-00-02 (per NEI, Ref. 6). This additional guidance contains:

1. Self-assessment guidance document
2. Appendix 1, actions for industry self assessment
3. Appendix 2, industry peer review subtier criteria.

February 2004

Standard Review plans are prepared for the guidance of the Office of Nuclear Reactor Regulation staff responsible for the review of applications to construct and operate nuclear power plants. These documents are made available to the public, as sections of NUREG-0800, as part of the NRC's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Standard review plans are not substitutes for regulatory guides or the NRC's regulations, and compliance with them is not required. The standard review plan sections are keyed to the Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants. Not all sections of the Standard Format have a corresponding review plan.

Requests for single copies of draft or active regulatory SRP sections (which may be reproduced) should be made to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301)415-2289; or by email to DISTRIBUTION@NRC.GOV. Electronic copies of this SRP are available through NRC's web site <www.nrc.gov> through the Electronic Reading Room, in the Document Collections, under Technical Reports (NUREGs) (NUREG-0800), and through ADAMS at the same web site, under Accession Number ML

Concerns regarding PRA quality and the standards development effort were discussed during the March 31, 2000, Commission briefing on the Risk-Informed Regulation Implementation Plan. The Commission, in their April 18, 2000, Staff Requirements Memorandum (SRM) (Ref. 7) on that briefing, indicated that the staff "should provide its recommendations to the Commission for addressing the issue of PRA quality until the ASME and ANS standards have been completed, including the potential role of an industry PRA certification process." In response to the Commission's SRM dated April 18, 2000, the staff issued SECY-00-162, "Addressing PRA Quality in Risk-Informed Activities" (Ref. 8), which described an approach for addressing PRA quality, including identification of the scope and minimal functional attributes necessary to ensure that the PRA information is adequate for its intended application in decision making. The Commission, in their October 27, 2000, SRM, indicated that the "... the timely resolution of PRA quality requirements is necessary to support existing and developing risk-informed regulation" (Ref. 9). This Standard Review Plan (SRP) Chapter 19.1 and the associated Regulatory Guide 1.200 (Ref. 10) have been developed in response to this SRM.

In developing this SRP chapter, the staff considered the NRC's guidance on the use of PRA in risk-informed regulatory applications as documented in Regulatory Guide 1.174 (Ref. 11) and the associated SRP Chapter 19 (Ref. 12). These documents make it clear that PRA information is one input into making a decision. Specifically, the decision-making process will use the results of the risk analyses in a manner that complements traditional engineering approaches, supports the defense-in-depth philosophy, and preserves safety margins. Thus, risk analysis will inform, but it will not determine regulatory decisions.

This SRP chapter concerns any licensee request submitted for NRC review and approval for which PRA can play an effective role in the decision-making process. It will be used to support application-specific SRP chapters that provide guidance for several activities, including the following examples:

- changes to a plant's licensing basis (SRP Chapter 19) (Ref. 13)
- changes to allowed outage times and surveillance test intervals in plant-specific technical specifications (SRP Chapter 16.1) (Ref. 14)
- changes in the scope and frequency of tests on pumps and valves in a licensee's in service test program (SRP Chapter 3.9.7) (Ref. 15)
- changes in the scope and frequency of inspections in a licensee's in service inspection program (draft SRP Chapter 3.9.8) (Ref. 16).

The above documents address reviewing the application in terms of the following:

- the structures, systems, and components (SSCs); operator actions; and plant operational characteristics affected by the application
- the description of the cause-effect relationships between the change and the above SSCs, operator actions, and plant operational characteristics
- mapping of the cause-effect relationships onto PRA model elements
- identification of the PRA results that will be used in the decision making
- the scope of risk contributors needed to support the decision

The documents also address issues related to limitations in scope of the PRA, etc.

However the PRA results are used, and whatever role they play in the decision making, the PRA analysis must be of sufficient quality to support that role. The existing SRP chapters give guidance on assessing the analysis of the impact of the change on the PRA results, but do not give specific guidance on assessing the adequacy of the base PRA. Regulatory Guide 1.200 and this SRP are being developed to fill that gap.

This SRP provides guidance to the NRC staff on determining the scope of review of the elements of a PRA analysis used to support a specific regulatory application, based on information provided by the licensee on the results of a comparison with an industry PRA standard or the results of a peer review performed in accordance with an industry approved peer review process. This SRP chapter is intended to be used in conjunction with an application-specific SRP such as SRP Chapter 19 (Ref. 12) or Chapter 3.9.8 (Ref. 16), which focus on the appropriate use of the PRA results in an integrated decision-making process. They may also be used to support novel applications in which the licensee is expected to identify how the PRA results are used to provide information to the decision makers.

This SRP chapter does not focus on the decision-making process itself, which is addressed in the application-specific SRP chapters.

REVIEW RESPONSIBILITIES

The technical nature of a licensee's request will determine which technical review branch in the NRC's Office of Nuclear Reactor Regulation (NRR) will serve as the primary review branch and, as such, have overall responsibility for leading the technical review, drafting the staff safety evaluation report (SER) or other appropriate regulatory document, and coordinating input from other technical review organizations.

The Probabilistic Safety Assessment Branch (SPSB) assists the primary review branch (upon request) by reviewing the PRA information and findings submitted by the licensee. Review support includes assessing the adequacy of the scope, level of detail, and quality of the PRA used by the licensee to support the regulatory change.

I. AREAS OF REVIEW

This SRP is intended to support the staff in its assessment of the technical adequacy of the PRA model used to generate results to support a risk-informed submittal. As such, it applies to all the parts¹ of a PRA that support the results.

II. ACCEPTANCE CRITERIA

In order for the NRC staff to conclude that a PRA is of sufficient technical adequacy to support an application, the staff needs to be assured that (1) the parts of the PRA needed to support the application have been appropriately identified and (2) those parts have been performed in a manner consistent with good industry practice. The former needs to be addressed as part of the assessment of the application. The latter can be met by determining that the necessary parts of the PRA have been performed in accordance with the staff position on consensus PRA standards or industry programs as documented in the appendices to Regulatory Guide 1.200. Where there are differences in approach to performing a specific part, the staff must determine that the approach used by the applicant is either equivalent to, or better than, that supported by the staff position.

¹ In this SRP, a part of a PRA can be understood as being equivalent to that piece of the analysis for which an applicable PRA standard identifies a supporting level requirement.

III. REVIEW GUIDANCE AND PROCEDURES

The objective of this SRP is to provide guidance to the NRC staff on how to determine that the PRA results being used in a decision are supported by the underlying analysis. It must be clear that the elements of the model used to generate those results are of sufficient technical quality and that the assumptions and uncertainties that have the potential to affect the results have been evaluated as being appropriate.

III.1 Scope of Review

In order to perform the review for quality, the reviewer should first understand the context in which the PRA is being used.

III.1.1 Use of the PRA in the Application

The reviewer should become familiar with the way the PRA is used in the application. This includes:

- identification of the SSCs, operator actions, and plant operational characteristics affected by the application
- a description of the cause-effect relationships between the change and the above SSCs, operator actions, and plant operational characteristics
- mapping of the cause-effect relationships onto PRA model elements
- definition of the acceptance criteria or guidelines, including identification of the PRA results that will be used to compare against the acceptance criteria or guidelines and how the comparison is to be made.

III.1.2 Scope of Risk Contributors Addressed in the PRA Model

Based on the definition of the application, the scope of risk contributors (internal and external initiating events, modes of plant operation) of the PRA can be identified. For example, if the application is designed around using the acceptance guidelines of Regulatory Guide 1.174, the evaluations of core damage frequency (CDF), Δ CDF, large early release frequency (LERF), and Δ LERF should be performed with a full-scope PRA, including external initiating events and all modes of operation. However, since most PRAs do not address this full scope, the decision makers must make allowances for these omissions. Examples of allowances include the introduction of compensatory measures, restriction of the implementation of the proposed change to the aspects of the plant covered by the risk model, and use of bounding arguments to cover the risk contributions not addressed by the model. This SRP does not address this aspect of decision making but is focused on what information should be provided. The reviewer's responsibility is to understand the scope of the PRA used in the decision making so that the appropriate appendices to Regulatory Guide 1.200 are identified as references for the review.

III.1.3 Parts of the PRA Model Used in Application

To assess the quality of the PRA input for a decision, the licensee identifies which parts of the PRA are called upon to provide the PRA results called for by the acceptance criteria. These include not only the logic model events onto which the cause-effect relationships are mapped, but also all the events that appear in the accident sequences in which the first group of elements appear and the parts of the analysis required to evaluate the necessary results. For some applications, this may be a limited set, but for others, e.g., risk-informing the scope of special treatment requirements, all parts of the PRA model are relevant.

In applying this SRP, the reviewer need only address those parts identified as being required to support the PRA results used.

III.2 Assessment of the PRA

The part of the PRA used for the application is assessed to determine whether it is of sufficient technical quality. There are two aspects to assessing the acceptability and adequacy of the PRA results. First, the underlying PRA must be technically sound. This implies that (1) the PRA model, or the parts of the model required to support the application, represent the as-built and as-operated plant, which in turn implies that the PRA is up to date and reflects the current design and operating practices, (2) the PRA logic model has been developed in a manner consistent with industry practice and it correctly reflects the dependencies of systems on one another and on operator actions, and (3) the probabilities and frequencies are estimated consistently with the definitions of the corresponding events of the logic model.

Second, the engineering analyses, assumptions, and approximations used in developing the PRA model must be appropriate and must demonstrate the robustness of the conclusions with respect to the uncertainties in the analysis. There are issues for which there is no consensus on analytical models or methods of analysis. Furthermore, PRAs are models, and in that sense the developers of those models rely on certain approximations to make the models manageable and on certain assumptions to address the uncertainties concerning the modeling of certain issues. This is recognized in the application-specific regulatory guides such as Regulatory Guide 1.174, which give guidance on how to address the uncertainties by, for instance, performing appropriate sensitivity analyses. This aspect is expected to be addressed in the application-specific regulatory guides and associated SRP chapters.

III.2.1 Determination That the PRA Model Is Current

When using risk insights based on a PRA model, the PRA model must be up to date and represent the current plant configuration and operating practices. The reviewer should confirm that the licensee has a process for updating and maintaining the PRA model that is consistent with the staff position on the process in the ASME PRA standard. The reviewer should confirm that the PRA has been revised to reflect any significant changes in design or operational practices (including operating procedures), and that the data used to estimate the parameters are current. This may be achieved by reviewing the licensee's description of their updating process and ascertaining that the licensee has adequately addressed recent plant modifications and operational changes that could have a significant impact on the results of the specific application that are not reflected in the current PRA model.

III.2.2 Assessment of the PRA Required by the Application

The parts of the PRA required by the application are to be assessed for technical adequacy. It is expected that a licensee using the standard or peer review process has taken account of the exceptions and clarifications found in the appendices of Regulatory Guide 1.200 and has documented the comparison with the relevant documents as endorsed. The reviewer is to focus on the elements that have deviations from, or discrepancies with, the requirements of the endorsed documents. The reviewer may make a judgment that the deviation or discrepancy leads to an equivalent to the requirements of the endorsed documents. Alternatively, the reviewer may determine that the issue needs to be addressed in the application-specific review, by determining that the licensee has given reasons as to why the discrepancies are not important, or provided a demonstration that the discrepancy has no significant impact on the results used in the decision.

III.2.3 Assessment of Engineering Analyses, Assumptions, and Approximations

Since the standards and industry PRA programs are not (or are not expected to be) prescriptive, there is some freedom on how to model certain issues in the PRA, so that different analysts may make different assumptions regarding these issues, yet the issues still meet the requirements of the standard or have been accepted by the peer review. The choice of a specific assumption or a particular approximation

may, however, influence the results of the PRA. The NRC staff needs to be confident that the conclusions drawn from the PRA are not invalidated by the use of specific assumptions. This is addressed primarily in the application-specific assessment through the use of sensitivity analyses. The identification of the important assumptions is addressed in the application-specific regulatory guides and SRP chapters. However, the staff should review the licensee's basis for those assumptions and their justification, taking into account the peer reviewers' assessment. The staff's focus should be on determining that the assumptions have been characterized appropriately so that there is sufficient information to conclude that the sensitivity studies performed to test the robustness of the conclusions are reasonable with respect to what is seen in industry practice.

IV. EVALUATION OF FINDINGS

The reviewer should provide documentation to conclude that the elements of the PRA required to produce the results have been performed in such a way that the PRA results are fully supportable.

IV.1 Assessment of PRA Against Industry Good Practice

The PRA elements are assessed to determine that they have been performed in a technically correct manner that conforms with industry good practices. This can be determined by an assessment that the PRA elements are performed consistently with the standard or peer review process as endorsed in the appendices to Regulatory Guide 1.200, or that, where a discrepancy exists, the approach used is equivalent to, or is superior to that referenced in the standard or peer review process document. Alternatively, the reviewer may rely on a demonstration that the impact on the results used in the application is not significant.

IV.2 Significant Assumptions and Approximations Assessed

The reviewer should be satisfied that the assumptions and approximations made to address the sources of uncertainty identified as having the potential to significantly impact the particular PRA results have been characterized in an acceptable manner given the current state of knowledge, and that the characterization has taken into account the results of the peer review.

V. IMPLEMENTATION

This SRP is intended to be used in conjunction with, and in support of, an application-specific SRP.

VI. REFERENCES

1. GAO, "Nuclear Regulation: Strategy Needed To Regulate Safety Using Information on Risk," GAO/RCED-99-95, U.S. General Accounting Office, March 1999.¹
2. American Society of Mechanical Engineers, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," ASME RA-S-2002, April 5, 2002.²
3. Nuclear Energy Institute, "Probabilistic Risk Assessment (PRA) Peer Review Process Guidance, NEI-00-02, Rev. A3, March 20, 2000.³
4. USNRC, SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," October 29, 1999.⁴
5. 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.
6. Letter from NEI, Anthony Pietrangelo, Director of Risk and Performance Based Regulation Nuclear Generation, to the USNRC, Scott Newberry, Director of the Division of Risk Analysis and Applications, August 16, 2002.
7. USNRC, Staff Requirements Memorandum (SRM), "Commission Briefing on Risk-Informed Regulation Implementation Plan (SECY-00-0062) on March 31, 2000," April 18, 2000.⁴
8. USNRC, "Addressing PRA Quality in Risk-Informed Activities," SECY-00-162, July 28, 2000.⁴
9. USNRC, SRM, regarding SECY-162, "Addressing PRA Quality In Risk-Informed Activities," October 27, 2000.⁴
10. USNRC, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," Draft Regulatory Guide DG-1122, September 2002.⁵

¹ Copies may be obtained from the General Accounting Office, 441 G Street, NW., Washington, DC 20548; phone (202)512-6000.

² Copies may be obtained from the American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990; phone (212)591-8500.

³ 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.

⁴ 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>.

11. USNRC, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.174, July 1998.⁵
12. USNRC, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," Chapter 19 of the Standard Review Plan, July 1998.⁵
13. USNRC, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," Chapter 19 of the Standard Review Plan, Revision 1, July 2002.⁵
14. USNRC, "Risk-Informed Decisionmaking: Technical Specifications," Chapter 16.1 of the Standard Review Plan, August 1998.⁵
15. USNRC, "Standard Review Plan for Risk-Informed Decision Making: In service Testing," Chapter 3.9.7 of the Standard Review Plan, August 1998.⁵
16. USNRC, "Standard Review Plan for the Review of Risk-Informed In service Inspection of Piping," Chapter 3.9.8 of the Standard Review Plan, September 2003.⁵

⁵ 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>.

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev.,
and Addendum Numbers, if any.)

NUREG-800

2. TITLE AND SUBTITLE

NUREG-0800 Chapter 19.1, "Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities"

3. DATE REPORT PUBLISHED

MONTH	YEAR
February	2004

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

NRR Staff

6. TYPE OF REPORT

7. PERIOD COVERED *(Inclusive Dates)*

8. PERFORMING ORGANIZATION - NAME AND ADDRESS *(If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)*

Division of Systems Safety and Analysis
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS *(If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)*

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This SRP chapter concerns any licensee request submitted for NRC review and approval for which PRA can play an effective role in the decision making process. It will be used to support application-specific SRP chapters that provide guidance for several activities, including changes to plant's licensing basis.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

SRP, PRA Quality, Probabilistic Safety Assessment

13. AVAILABILITY STATEMENT

unlimited

14. SECURITY CLASSIFICATION

(This Page)

unclassified

(This Report)

unclassified

15. NUMBER OF PAGES

16. PRICE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS