September 29, 2006

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Stephen D. Dingbaum **/RA/**
Assistant Inspector General for Audits

SUBJECT: EVALUATION OF NRC'S USE OF PROBABILISTIC RISK ASSESSMENT (PRA) IN REGULATING THE COMMERCIAL NUCLEAR POWER INDUSTRY (OIG-06-A-24)

Attached please find the Office of the Inspector General's report, *Evaluation of NRC's Use of Probabilistic Risk Assessment (PRA) in Regulating the Commercial Nuclear Power Industry.* This report reflects the results of the evaluation performed by Scientech, LLC, on behalf of the NRC Office of the Inspector General.

At an exit conference on September 8, 2006, NRC officials agreed with the report's findings and opted not to submit formal written comments.

As a supplement to this Scientech report, OIG conducted its own review of historical documents and information surrounding the use of risk in regulation at NRC to more clearly understand how PRA fits into NRC's use of risk regulation. In September 2006, OIG issued a report, *Perspective on NRC's PRA Policy Statement (OIG-06-A-25)*, identifying key historical underpinnings of risk-informed regulation at NRC.

If you have any questions or wish to discuss this report, please call me at 415-5915 or Anthony Lipuma at 415-5911.

Attachment: As stated

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EVALUATION REPORT

Evaluation of NRC's Use of Probabilistic Risk Assessment (PRA) in Regulating the Commercial Nuclear Power Industry

OIG-06-A-24 September 29, 2006

Final Report

Evaluation of NRC's Use of Probabilistic Risk Assessment (PRA) In Regulating the Commercial Nuclear Power Industry

August 2006

SCIENTECH®

200 S. Woodruff Avenue
Idaho Falls, ID 83401

EXECUTIVE SUMMARY

BACKGROUND

The Nuclear Regulatory Commission (NRC) uses Probabilistic Risk Assessment (PRA) in the regulatory process. This use has influenced several regulatory areas, including rulemaking, licensing, the reactor oversight process (ROP), enforcement and enforcement discretion. PRA has been used by industry and NRC since the 1970's. In 1995, to clarify expectations on the usage of PRA, the Commission issued the PRA Policy Statement to encourage the use of PRA and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the art in terms of methods and data.

PRA is a methodology which is used to answer three questions:

1. What can happen?
2. What is the likelihood?
3. What are the consequences?

Unlike deterministic analysis that is based on applying experience, testing programs and expert judgment, PRA develops a quantitative estimate of risk by evaluating the frequency of initiating events, the conditional probability of the unavailability and the unreliability of systems, structures and components (SSCs) available to mitigate an initiating event, and the reliability of human interaction with SSCs. In addition, PRA extends the deterministic approach by examining multiple failures and unavailabilities of SSCs. Typically the results of a PRA are presented as core damage frequency (CDF) and large early release frequency (LERF), the contributors to these estimated results, and the corresponding uncertainties in the estimated results.

PURPOSE

The objectives of this evaluation were to:

- Determine if NRC is following prevailing good practices[1] in PRA methods and data in its use of PRA,
- Determine if NRC is using prevailing good practices in PRA methods and data appropriately in its regulation of licensees, and
- Determine if NRC is achieving the objectives of its PRA policy statement.

This evaluation addresses only the NRC's regulation of operating commercial power plants.

[1] "Prevailing good practices" were used in the evaluation in lieu of the NRC PRA Policy Statement term "state-of-the-art." A Prevailing Good Practices for PRA document was developed as part of this project in order to support the evaluation. Note that prevailing good practices are described in Section II, and Appendix B provides a summary of the prevailing good practices.

RESULTS IN BRIEF

The NRC has expended considerable effort and initiative to achieve the objectives of the PRA Policy Statement since it was issued in 1995. The agency has developed a number of PRA specific programs and PRA has been applied in multiple other programs and activities.

The following table summarizes the evaluation results.

Table ES-1
Summary of Evaluation Results

Evaluation Objective	Evaluation Result
Determine if NRC is using prevailing good practices[2] in PRA methods and data in its use of PRA	Although NRC is employing prevailing good practices in the areas evaluated in this report, the agency lacks formal, documented processes and associated configuration control for its PRA models and software. The evaluation found some instances where better control would be appropriate and where new standards/approaches are planned to be developed and issued, either by the agency or industry organizations such as the American Nuclear Society (ANS) and American Society of Mechanical Engineers (ASME). Specific findings in this area are: ➢ SPAR models need improved configuration control. ➢ Quality assurance requirements for SAPHIRE and GEM software need to be defined and software control procedures implemented. Recommendations are provided to improve on these two findings in Section III.
Determine if NRC is using prevailing good practices in PRA methods appropriately in its regulation of licensees	Although NRC is using PRA appropriately in the areas evaluated for this report, there are instances where increased technical review would be appropriate. Because these instances are not a major departure from the requirements disclosed during the evaluation, they are provided as suggested areas for consideration for NRC action. Areas for consideration are contained in Section IV.
Determine if NRC is achieving the objectives of its PRA Policy Statement	A primary objective of the PRA Policy Statement is to increase the use of PRA. As such, NRC has undertaken a number of PRA initiatives to further the use and application of PRA consistent with the PRA policy statement. However, this evaluation did not assess the effectiveness of these efforts.

[2] See Footnote 1.

As stated in the table above, the two findings[3] identified in the evaluation are:

- SPAR models need improved configuration control.
- Quality assurance requirements for the SAPHIRE and GEM software need to be defined and software control procedures implemented.

SPAR Models Need Improved Configuration Control

The NRC has developed Standardized Plant Analysis Risk (SPAR) models for estimating plant risk due to equipment failures and operational events. SPAR models consist of logical representations of power plant SSCs (using fault trees and event trees with initiating event and component failure data) as well as documentation that describes the models. SPAR models are used to support the ROP, the Accident Sequence Precursor (ASP) Program, and the Generic Safety Issue resolution process. SPAR models are also used to perform analyses in support of the staff's risk-informed reviews of license amendments, as well as to independently verify the Mitigating Systems Performance Index (MSPI).

It was found that the SPAR model documentation lags the availability of the SPAR computer models. The prevailing good practices for PRA model documentation are primarily based upon the American Society of Mechanical Engineers (ASME), "Standard for Probabilistic Risk Assessment for Nuclear Power Plants," which has also been incorporated to a large degree in NRC Regulatory Guide (RG) 1.200 For Trial Use, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities."

The prevailing good practices for PRA configuration control documentation are intended to assure that the documentation is adequate to "demonstrate that the PRA is being maintained consistently with the as-built, as-operated plant…"[4] and that "the sources of information used in the PRA are both referenced and retrievable"[5].

The SPAR models are used by the Senior Reactor Analysts in the regions as well as by headquarters staff. We understand that the agency plans to maintain the models on the basis of specific application needs. For example, when addressing a finding during the significance determination process (SDP), the licensee would be requested to provide any changes which could significantly impact the assessment. Over time, the standard SPAR models are revised to reflect each specific plant by addition of more detail as well as to reflect experiences gained in the application of the models or up-to-date failure data. This evaluation found that some of the SPAR models being applied in the regions were a more recent version than had been fully

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[3] A finding is defined as a nonconformance, disclosed during the course of an evaluation, which requires written response indicating a corrective action plan and a schedule for implementation. An observation is defined as an isolated/minor departure from requirements disclosed during the course of an evaluation which, if not addressed, could lead to deficiencies or nonconformances in the future. In addition, observations are provided which are either positive attributes or areas where improvement should be considered.

[4] ASME RA-S-2002, including Addenda ASME RA-Sb-2005, "Standard to Probabilistic Risk Assessment for Nuclear Power Plant Applications."

[5] Regulatory Guide 1.200 for Trial Use, February 2004, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk Informed Activities."

documented. The model documentation identifying changes to the earlier model version had not yet been provided for the model being used in the regions.

Thus, even though the most current model may be in use, the documentation of the model to describe modeling and/or data assumptions and changes from previous revisions of the PRA models has lagged the availability of the SPAR models. This could lead to an inconsistency in evaluations and is not consistent with the prevailing good practices.

SAPHIRE and GEM Software Need Improved Configuration Control Procedures Implemented

The Systems Analysis Program for Hands-On Integrated Reliability Evaluations (SAPHIRE) and Graphical Evaluation Module (GEM) software programs are used to perform evaluations of the SPAR Models and provide risk results based on the events or initiators being evaluated. The quality assurance requirements for these software codes could not be fully determined and the program for compliance is not well defined.

The prevailing good practice for software control is described in the ASME PRA standard that states the computer codes used to support and to perform PRA analysis shall be controlled to ensure consistent, reproducible results and there should be a process to maintain configuration control.

Given the level of usage and number of plant specific SPAR models being analyzed using SAPHIRE and GEM, the quality assurance program for the software would be expected to be in accordance with prevailing good practices and fully documented. While most portions of a quality assurance program for software development and maintenance appear to be present, the prevailing good practices for PRA documentation, that includes software and maintenance, are not being followed for SAPHIRE AND GEM.

These findings are discussed in detail in Section III. In addition, several observations (both positive and negative) from the evaluation are documented in Section IV.

RECOMMENDATIONS

Three recommendations to address the two findings are provided in Section III. A consolidated list of areas for consideration is provided in Section IV.

ABBREVIATIONS AND ACRONYMS

ANS	American Nuclear Society
ASP	accident sequence precursor
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	Code of Federal Regulations
EF	effectiveness initiatives and activities
GEM	Graphical Evaluation Module
IEEE	Institute of Electrical and Electronics Engineers
LERF	large early release frequency
LOCA	loss-of-coolant accident
LP/SD	low power and shutdown
MSPI	Mitigating System Performance Index
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
PRA	probabilistic risk assessment
RG	regulatory guide
RIRIP	Risk-Informed Regulation Implementation Plan
ROP	Reactor Oversight Process
SA	safety initiatives and activities
SAPHIRE	Systems Analysis Program for Hands-On Integrated Reliability Evaluation
SDP	significance determination process
SPAR	Standardized Plant Analysis Risk
SRA	Senior Reactor Analyst
SSC	systems, structures and components
V&V	verification and validation

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I. BACKGROUND

PRA has been used by industry and NRC since the 1970's. The NRC uses PRA in the regulatory process. This use has influenced several regulatory areas including:

- rulemaking
- licensing
- ROP
- enforcement
- enforcement discretion

PRA is a methodology which is used to answer three questions: 1. What can happen? 2. What is the likelihood? 3. What are the consequences?

Unlike deterministic analysis that is based on applying experience, testing programs and expert judgment, PRA develops a quantitative estimate of risk by evaluating the frequency of initiating events, the conditional probability of the unavailability and the unreliability of SSCs available to mitigate an initiating event, and the reliability of human interaction with SSCs. In addition, PRA extends the deterministic approach by examining multiple failures and unavailabilities of SSCs. Typically the results of a PRA are presented as CDF and LERF, the contributors to these estimated results, and the corresponding uncertainties in the estimated results.

In 1995, to clarify expectations on the usage of PRA, the Commission issued the PRA Policy Statement[6] to encourage the use of PRA and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the art in terms of methods and data. Specific elements from the PRA Policy Statement are:

1. Increasing the use of PRA technology in all regulatory matters 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 and supports the NRC's traditional defense-in-depth philosophy.

2. Using PRA and associated analysis in regulatory matters to:

    a. Reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices, and
    b. Support proposals for additional regulatory requirements in accordance with 10 Code of Federal Regulations (CFR) 50.109 (Backfit Rule).

    This includes developing and following appropriate procedures for including PRA in the process for changing regulatory requirements.

3. Developing PRA evaluations to be as realistic as practicable, with appropriate supporting data being publicly available for review.

[6] "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," Published August 16, 1995.

4. Using the Commission's safety goals for nuclear power plants and subsidiary numerical objectives with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

Section II of this report describes the purpose of the evaluation, Section III presents the findings and recommendations, and Section IV contains the evaluation results, observations, and areas for consideration. Appendix A describes the scope and methodology of the evaluation and Appendix B summarizes the PRA prevailing good practices used in the evaluation.

II. PURPOSE OF EVALUATION

The purpose of this evaluation was to conduct an independent review of the NRC's use of PRA. The specific objectives of the evaluation were to:

- Determine if NRC is following prevailing good practices[7] in PRA methods and data in their use of PRA,
- Determine if NRC is using prevailing good practices in PRA methods appropriately in its regulation of licensees, and
- Determine if NRC is achieving the objectives of its PRA policy statement.

This evaluation addresses only the NRC's regulation of operating commercial power plants. Appendix A contains the scope and methodology of the evaluation.

[7] "Prevailing good practices" are included in the evaluation in lieu of the NRC PRA Policy Statement term "state-of-the-art" because "state-of-the-art" implies the use of leading edge technology for which there may not be extensive experience or standards. The evaluation assumed that the overall intention of the PRA Policy Statement was to use PRA methods, data and tools that had a technically sound and defensible basis that are defined here as "prevailing good practices".

III. FINDINGS

This section describes the findings from the evaluation that reviewed PRA use and application in the NRC. A finding is defined as a nonconformance, disclosed during the course of the evaluation, which requires written response indicating a corrective action plan and a schedule for implementation.

The evaluation identified two findings:

- SPAR models need improved configuration control.
- Quality assurance requirements for the SAPHIRE and GEM software need to be defined and software control procedures implemented.

A. SPAR Models Need Improved Configuration Control

NRC has developed Standardized Plant Analysis Risk (SPAR) models for each operating reactor type. SPAR models consist of a logical representation (using fault trees and event trees with data) of the plant systems as well as documentation that describes the models. SPAR models are used to support the ROP, the ASP Program, and the Generic Safety Issue resolution process. SPAR models are also used to perform analyses in support of the staff's risk-informed reviews of license amendments, as well as to independently verify the Mitigating Systems Performance Index (MSPI).

Finding

The evaluation found that some SPAR models being used for evaluations in the regions had not been fully documented in a timely manner after changes were made to the model to make corrections or to enhance the models (lagging on the order of a month or more in some cases). Thus, even though the most current model may be in use, the documentation of the model to describe modeling and or data assumptions and changes from previous revisions of the PRA models has lagged the availability of the SPAR models. This is not consistent with the prevailing good practice for PRA model configuration control and documentation and is caused by the lack of a formal process for maintaining the models and documentation. The models being used should be fully documented by the controlling organization (the Office of Nuclear Regulatory Research and its contractor) before being made available to the users of the models (regional staff and headquarters PRA practitioners).

Basis of Finding

The prevailing good practice for PRA model documentation is primarily based upon the American Society of Mechanical Engineers, ASME, "Standard for Probabilistic Risk Assessment for Nuclear Power Plants," which has also been incorporated to a large degree in NRC RG 1.200 for Trial Use, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities."

The prevailing good practice for PRA configuration control documentation is intended to assure that the documentation is adequate to "demonstrate that the PRA is being maintained consistently with the as-built, as-operated plant…"[8] and that "the sources of information used in the PRA are both referenced and retrievable."[9]

The SPAR models are used by the Senior Reactor Analysts in the regions as well as by headquarters staff. The Level 1 PRA SPAR models are a standardized, plant-specific set of PRA models that use the event tree/fault tree linking methodology and use an NRC-developed standard set of event trees and standardized input data. This data includes initiating event frequencies, equipment performance, and human performance with the intention that the input data may be modified to be more plant- and event-specific as resources are available. These SPAR models are evaluated using the SAPHIRE software, and the associated GEM software.

Over time, the standard SPAR models are revised to reflect each specific plant by addition of more detail as well as to reflect experiences gained in the application of the models or up-to-date failure data. This evaluation found that some of the SPAR models being applied in the regions were a more recent version than had been fully documented. The model documentation identifying changes to the earlier model version had not yet been provided for the model being used in the regions. Thus, even though the most current model may be in use, the documentation of the model to describe modeling and or data assumptions and changes from previous revisions of the PRA models has lagged the availability of the SPAR model. Control of the SPAR models is not governed by formal procedures. The SPAR models are the responsibility of the Office of Nuclear Regulatory Research and most update work is performed by an NRC contractor, Idaho National Laboratory.

PRA models, including SPAR models, are updated, refined and revised on a periodic basis to more closely reflect each specific plant by addition of more detail as well as to reflect experiences gained in the application of the models or up-to-date failure data. These model updates can include logic changes and data changes as well as adding more detailed information on the SSCs. However, the refinement and maintenance of models and documentation that sufficiently represent as-built, as operated conditions (for example ASP, ROP and event evaluations) should be performed within a formal, documented plan for model updating and configuration control. This overall plan was not found during the evaluation. The level of effort needed to maintain such models representative of the as-built, as-operated plant can be substantial. We understand that the agency plans to maintain the models on the basis of specific application needs. For example, when addressing a finding during the SDP process, the licensee would be requested to provide any changes which could significantly impact the assessment.

The prevailing good practice for PRA model maintenance and configuration control is described in the ASME PRA Standard, Section 5.4, "PRA Maintenance and Upgrades", and Section 5.8 "Documentation". The ASME PRA standard states that the documentation *"typically includes:*

[8] ASME RA-S-2002, including Addenda ASME RA-Sb-2005, "Standard to Probabilistic Risk Assessment for Nuclear Power Plant Applications."
[9] Regulatory Guide 1.200 for Trial Use, February 2004, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk Informed Activities."

a. *a description of the process used to monitor inputs and collect new information,*
b. *evidence that the aforementioned process is active,*
c. *descriptions of proposed changes,*
d. *description of changes in a PRA due to each PRA upgrade or PRA maintenance,*
e. *record of the performance and results of the appropriate PRA reviews,*
f. *record of the process and results used to address the cumulative impact of pending changes,*
g. *record of the process and results used to evaluate changes on previously implemented risk informed decisions,*
h. *description of the process used to maintain software configuration control.*"

The SPAR models have continued to evolve as the need arises for evaluation of plant events and incidents. The changes made to the model to establish the Revision 3P of the SPAR models are in most cases defined in the detailed implementation steps of the SPAR Model Cutset Review Process Guidelines and conform to the prevailing good practices for PRA models for the portions that they modify with the changes documented in the SPAR model documentation. The guidelines assume a high level of familiarity with PRA terminology, techniques, tools, and with interpreting analysis results. The guidelines do not specify the required level of expertise, nor are there any specific references to documents which specify the level of personnel which are to perform work on or review the models.

The model custodian follows most elements of the prevailing good practices discussed above to maintain control of the models. He maintains the official model and he is the only person with access. He maintains a web-based "SPAR Model Change Logging System," and two additional documents, "Outstanding SPAR Model Issues.doc" and "SPAR Model Checklist.doc". The SPAR Model Change Logging System is accessible to allow user feedback. The system allows suggestions to update the model, to correct errors and suggest enhancements. The "Outstanding SPAR Model Issues.doc" maintains a list of items, both generic and plant specific, which have been determined to be needed to keep the SPAR models current and up to date. There does not appear to be a formal process to assure that the model reflects the current as-operated plant, although the process makes an effort to keep the models current. The "SPAR Model Checklist.doc" provides general guidance for maintaining consistency from plant to plant. Any changes to the model are discussed with the custodian and he has final review of any changes before the model is placed in the system. He is the individual who releases the model for use. Although not a formally documented practice, based on the review of multiple documents and models, the control of the SPAR models does address elements of the prevailing good practices for PRA model configuration control.

Configuration control of the SPAR models is important because they are used in the SDP, ASP, MSPI and other applications and relied upon, at least in part, to support regulatory decisions.

Recommendation

1. Develop and implement a formal, written process for maintaining PRA models that are sufficiently representative of the as-built, as-operated plant to support model uses.

B. SAPHIRE and GEM Software Need Improved Configuration Control Procedures Implemented

The SAPHIRE and GEM software programs are used to evaluate the SPAR Models.

Finding

Software quality assurance must be planned for and managed effectively to ensure success. However, quality assurance requirements for the SAPHIRE and GEM software codes could not be determined and the program for compliance is not well defined. Many parts of a quality assurance program exist and are being applied, but not within a defined process. Further, changes to the software codes are not fully documented and tested.

Basis of Finding

The prevailing good practice for software control is described in the ASME PRA standard that states the computer codes used to support and to perform PRA analysis shall be controlled to ensure consistent, reproducible results and there should be a process to maintain configuration control. Any changes to the computer codes should be fully documented and tested.

Given the level of usage and number of plant models being analyzed using SAPHIRE and GEM, the quality assurance program for the software should be in accordance with prevailing good practices and fully documented. While most portions of a quality assurance program for software development and maintenance appear to be present, the prevailing good practices for PRA software maintenance are not being followed.

Several documents related to SAPHIRE and GEM were reviewed as part of this evaluation and include:

- The SAPHIRE version 7 Users Manual – The manual is typical of on-line help guides with a folder-type hierarchy structure devoid of section numbers (which would be useful to the user).
- GEM Reference Manual - The manual is typical of on-line help guides with a folder-type hierarchy structure devoid of section numbers (which would be useful to the user). There is no discussion of quality assurance.
- Memo on SAPHIRE Quality Assurance Methodology - The process for version control, bug fixes, new features, and testing is outlined. This is an informal document with no document number or reference.
- SAPHIRE Change Design and Testing Procedure - This document outlines the general approach used for software development and testing. The document also contains design change forms, testing forms, and a testing checklist.
- SAPHIRE changes for the current version - The listing addresses changes between 08-28-99 and 10-04-05.
- EXCEL spreadsheet documentation of changes made to SAPHIRE (Change Form Log).
- History of changes to the code - The history includes the revision number, name, date, author, and description.

- Testing, verification, and validation report for SAPHIRE versions 6.0 and 7.0.

Only one quality assurance standard is discussed or referenced in the materials reviewed. This standard is Institute of Electrical and Electronics Engineers (IEEE) 1012-1986, "Standard for Software Verification and Validation Plans," which was used in testing SAPHIRE versions 4.0 and 5.0. The testing was performed by the software developer, Idaho National Laboratory under contract to NRC. Software testing is the process of identifying program errors by analysis or by executing programs on a computer using actual or test data. The objective of testing is to find and correct errors before the software applications are put into operation. All software applications acquired or revised should be tested to ensure it satisfies user needs and is error free.

Version 5.0 of SAPHIRE underwent a formal verification and validation process, as documented in NUREG/CR-6116, volume 9, "Systems Analysis Programs for Hands-On Integrated Reliability Evaluations (SAPHIRE) Version 5.0 Verification and Validation (V&V) Manual" that was consistent with prevailing good practices.

Version 7.2 is the current version of SAPHIRE. The testing approach for Versions 6.0 and 7.0 is documented in NUREG/CR-6688, "Testing, Verifying, and Validating SAPHIRE Versions 6.0 and 7.0". This report describes that a testing-based verification and validation process was created for SAPHIRE. Versions 6.0 and 7.0 are "tested" by performing comparison runs with version 5.0 and making corrections as necessary. The testing performed does not reference a quality assurance standard other than IEEE 1012-1986. The users' manual states that the simplified form of verification and validation focused resources on code testing and defends this approach with the statement: "However, this V&V process (used for versions 4.0 and 5.0) was found not to be cost-effective because it uses most of the available resources for documentation rather than actual testing."

This form of V&V is not consistent with prevailing good practices. Without formal documentation of the testing, assurance that the code has been properly tested is reduced. For example, if new features are added to the code, comparing the results with previous versions would not exercise the new feature. Since Beta testing is not documented, verification that all new features have been reasonably tested is not possible. Another example would be an increase in code limits; comparing the results with previous versions would not test the new limits or problems that could result if the new limits are exceeded.

It is well recognized that documentation is time and resource intensive, and that this is expected of a quality assurance task, unless an alternative, equivalent approach is used. An equivalence basis should be provided that meets the intent of software quality practices

The process and documentation for proposed changes and identified bugs in SAPHIRE appears to be reasonable. Forms are available for proposed code changes and to report bugs identified in the code. While most elements of a quality assurance program consistent with the prevailing good practices are in place and appear to be implemented, the reviewers did not find evidence of the overall quality assurance requirements nor a program for compliance with that requirement. A quality assurance program that helps assure correct calculations is important because the SAPHIRE and GEM software is used to evaluate SPAR Models that are used for SDP, ASP, MSPI and other applications and relied upon, at least in part, to support regulatory decisions.

Recommendations

2. Develop and implement a fully documented process to conduct and maintain configuration control of PRA software (i.e., SAPHIRE, GEM).

3. Conduct a full verification and validation of SAPHIRE version 7.2 and GEM.

C. Consolidated List of Recommendations

1. Develop and implement a formal, written process for maintaining PRA models that are sufficiently representative of the as-built, as-operated plant to support model uses.

2. Develop and implement a fully documented process to conduct and maintain configuration control of PRA software (i.e., SAPHIRE, GEM).

3. Conduct a full verification and validation of SAPHIRE version 7.2 and GEM.

IV. ASSESSMENT RESULTS, OBSERVATIONS AND AREAS FOR CONSIDERATION

This section provides an assessment of the evaluation results with the evaluation objectives, positive observations, and summary of observations and areas for consideration.

A. Assessment of Results with Evaluation Objectives

A summary of the assessment compared to the objectives of the evaluation is provided in this section. Areas have been identified that the agency should continue to actively seek improvements, and act on the findings discussed in Section III.

Determine if NRC is using prevailing good practices in PRA methods and data in their use of PRA

Overall, the agency has used prevailing good practices in its PRA and risk-informed activities. However, the application reviews performed indicated that quality assurance standards and programs for implementing those standards do not appear to be fully defined or documented. The evaluation found some instances where better control would be appropriate and where new standards /approaches are planned to be developed and issued, either by the agency or industry organizations such as ANS and ASME.

Specific findings in this area and that are documented in Section III are:

- SPAR models need improved configuration control.
- Quality assurance requirements for SAPHIRE and GEM software need to be defined and software control procedures implemented.

Determine if NRC is using PRA methods and data appropriately in its regulation of licensees

Overall, the agency is using PRA appropriately. The evaluation identified some instances where increased technical review would be appropriate. Observations and areas for consideration are discussed later in this section.

Determine if NRC is achieving the objectives of its PRA Policy Statement

NRC has largely achieved the objectives of the PRA Policy Statement as shown in Table IV-1. Significant effort has been expended by the NRC into developing and applying risk informed approaches since 1995. Determination of the efficiency of achievement was beyond the scope of this evaluation. Table IV-1 provides a summary of the agency's performance relative to key aspects of the PRA Policy Statement.

Table IV-1
Evaluation of NRC achievement of PRA Policy Statement

PRA Policy Statement Area	Evaluation Discussion
PRA technology 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 and supports the NRC's traditional defense-in-depth philosophy.	The use of PRA has been increased in the Office of Nuclear Reactor Regulation, the Office of Nuclear Regulatory Research, and the regional offices. There are multiple uses of PRA, including the Individual Plant Examination Program, where vulnerabilities were identified and acted on (Pre-PRA Policy Statement), Anticipated Transient without Scram rule (Pre-PRA Policy Statement), Station Blackout (Pre-PRA Policy Statement), Maintenance Rule, Revised Reactor Oversight Process, Shutdown Risk Management (Pre-PRA Policy Statement), Improvements in Technical Specifications, Inservice Inspection, Inservice Testing, treatment of non-nuclear safety SSCs for advanced reactors, and fire protection. These uses have aimed at either reducing risk, where cost beneficial, or changing requirements which were unnecessarily burdensome. The agency is using PRA extensively at headquarters and the regional offices. The reviews of guidance documents and technical analyses provide extensive documentation that PRA use within the agency is extensive. Efficiency and gaining consensus in the combined use of traditional and PRA approaches (risk-informed approach) to decision making continues to be a challenge (which is to be expected).
Where practical, and within the bounds of the state-of-the-art, use PRA to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices.	As noted above, examples include Inservice Inspection, Technical Specifications, fire protection, and the Revised Reactor Oversight Process. 10 CFR50.69 and 10 CFR 50.46a are ongoing, significant topics where consensus has not yet been reached. Future events will determine if these two initiatives are successful in reducing unnecessary conservatism in a cost-effective manner. In addition, activities are in progress and planned to review existing regulations from a risk informed perspective, in order to improve the regulatory process. This includes the Part 53 initiative, which would be an alternative to Part 50.
Where appropriate, use PRA to support proposals for additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule).	NRC continues to review and assess the risk significance of operating experience (e.g. the Accident Sequence Precursor (ASP) program) and generic issues, such as containment sump performance, using PRA as an input. Risk significance, using PRA input, is a key factor in regulatory decision making. Examples include: The Individual Plant Examination Program, where vulnerabilities were identified and acted on (Pre-PRA Policy Statement), Anticipated Transient Without Scram rule (Pre PRA Policy Statement), Station Blackout (Pre-PRA Policy Statement), Maintenance Rule, treatment of non-nuclear safety equipment for advanced reactors, and fire protection.

Table IV-1
Evaluation of NRC achievement of PRA Policy Statement

PRA Policy Statement Area	Evaluation Discussion
Develop and follow appropriate procedures for including PRA in the process for changing regulatory requirements.	Several procedures and regulatory guides have been developed to support the development and application of PRA. A major ongoing activity is the development of industry standards for all key PRA aspects and the development/adaptation of corresponding regulatory guides. This activity is expected to improve the quality and efficiency of PRA development and application. The agency has been a major contributor to the development of standards and guidelines for developing and using PRA.
Develop PRA evaluations to be as realistic as practicable, with appropriate supporting data being publicly available for review.	Evaluations reviewed tended to be appropriately realistic. The consideration of uncertainties and the scope of PRA models remains a challenge. Also important is the clear identification and documentation of aspects of a decision which are either not included in the PRA analysis or which are not amenable to PRA analyses. NRC has an active, ongoing program to enhance the processes and methods for addressing uncertainties and scope of PRA model and analyses.
Use the Commission's safety goals for nuclear power plants and subsidiary numerical objectives, with appropriate consideration of uncertainties.	Surrogate metrics such as CDF and LERF are the primary means for assessing risk significance. These surrogate goals have been demonstrated to be consistent with the safety goals and are practical metrics for routine applications. Regulatory Guides developed by the agency address uncertainties and deterministic measures, such as defense-in-depth and safety margins, in developing risk-informed inputs to a decision.

B. Observations

This section presents the observations from the evaluation. The agency and industry have several fundamental challenges and opportunities to continue to benefit from a risk-informed, performance-based approach to managing safety and resources. These are neither new nor unfamiliar; and the agency has taken prior actions, and has actions in-place or planned.

An observation is defined as an isolated/minor departure from requirements disclosed during the course of an evaluation which, if not addressed could lead to deficiencies or nonconformances in the future. In addition, observations are provided which are either positive attributes or areas where improvement should be considered. Suggested areas for consideration for NRC action are provided where appropriate.

Observation: ***Positive PRA Environment***

Staff and Management interviewed openly shared opinions on PRA Application and Usage.

Area for Consideration: None

Observation: ***Good PRA Acceptance***

PRA appears to be well accepted in the regions as part of "doing business" in accordance with defined programs. It is apparent that PRA is an integral part of the Reactor Oversight Process, SDP, Maintenance Rule, and other programs.

Area for Consideration: None

Observation: ***PRA Quality***

Reviews conducted indicated varying approaches to the quality of models and data. While no instances were found of PRA quality problems, a standard approach to PRA quality should be considered.

Area for Consideration:

1. Consider implementing a requirement that all PRA within NRC be performed in accordance with existing or developed guidance documents and standards, as they become available and as they are applicable.

Observation: ***SRA Training***

A position of senior reactor analyst (SRA) has been created. Each region has at least two SRAs, with an aim to have three SRAs. SRA training requirements are documented in MC 1245, Appendix D1. The SRAs are a key element of implementation of the PRA Policy statement. The SRA Training Program leading to certification is well thought of and, based on this evaluation, appears effective. Maintaining the skills of the SRAs might benefit from a requalification program and continuing/advanced courses.

Area for Consideration:

2. Consider implementing a continuing education program for the SRAs.

Observation: ***PRA Uncertainty***

Although all analyses have uncertainty, PRA analyses have a shorter history and fewer experts than many of the traditional engineering disciplines. Some expressed concerns with the manner in which uncertainties were considered in decision-making. Also important is the clear identification and documentation of aspects of a decision which are either not included in the PRA analysis or which are not amenable to PRA analyses (e.g., the impact of testing to demonstrate that calculations adequately represent the plant response to events).

Area for Consideration:

3. Consider development of a more formal process for identifying and addressing uncertainties, especially when the uncertainty in the analysis is high. In addition to considering uncertainties amenable to PRA characterization, this process should:
    a. Clearly identify and document the aspects of a decision which are either not included in the PRA analysis or which are not amenable to PRA analyses (e.g., the impact of testing to demonstrate that calculations adequately represent the plant response to events),

b. Be understandable, at its basic level, by non-PRA practitioners, including management, so as to provide additional assurance that decisions are made within the proper context of the uncertainty, and
c. Consider the shared role of PRA and deterministic approaches.

Observation: ***Role of PRA***

Not unexpectedly, and consistent with Industry experience, the acceptance and views on the use of PRA varies, from exceptionally strong to exceptionally questioning. The review and decision-making processes in place at NRC appear fully capable of managing the potential for misapplication, but with the expected adverse effect of increased schedule and resource requirements. While PRA is generally well accepted as stated above, there remains a skeptical minority as well as a healthy concern that PRA be applied consistently and appropriately.

Area for Consideration:

4. Consider developing and implementing training to address staffing changes, continuous staff development, and to bridge the gap between PRA and deterministic backgrounds.

Observation: ***PRA Strengths and Limitations Training***

Some interviewees suggested that the NRC should develop training that addresses the cultural concerns with using PRA for regulatory issues. This training could do more to discuss the strengths and limitations of the PRA, when it is most appropriate to use PRA and when it is more appropriate to use traditional methods, and the relationship of PRA scope and approach to traditional approaches. There is currently not a course to address this.

Area for Consideration:

5. Develop a PRA strengths and limitations course and establish requirements for taking the course.

Observation: ***PRA Training Course Frequency***

PRA Training courses are extensive but offered on an infrequent basis (usually once per year) due to small number of attendees.

Area for Consideration:

6. Consider enhancing the current PRA Training program to explicitly address the relationship of deterministic, PRA and risk-informed practices. In addition this training should consider uncertainties and scope as noted above. Should also consider adapting some courses to video / electronic training media so that they can be offered more frequently.

Observation: ***Differing Professional Opinion Process***

The agency has several well designed programs in place to allow staff to express concern if they feel that PRA is being misapplied. At the lowest level, the agency appears to be open to informal discussions between participants to voice dissenting opinions. At a more formal level, there is a non-concurrence process and a differing professional opinion process which allows staff to raise the issue to higher levels of management. These processes appear to be well designed and are encouraged to be used.

Area for Consideration: None

Consolidated Areas for Consideration

1. Consider implementing a requirement that all PRA within NRC be performed in accordance with existing or developed guidance documents and standards, as they become available and as they are applicable.

2. Consider implementing a continuing education program for the SRAs.

3. Consider development of a more formal process for identifying and addressing uncertainties, especially when the uncertainty in the analysis is high. In addition to considering uncertainties amenable to PRA characterization, this process should:
   a. Clearly identify and document the aspects of a decision which are either not included in the PRA analysis or which are not amenable to PRA analyses (e.g., the impact of testing to demonstrate that calculations adequately represent the plant response to events),
   b. Be understandable, at its basic level, by non-PRA practitioners, including management, so as to provide additional assurance that decisions are made within the proper context of the uncertainty, and
   c. Consider the shared role of PRA and deterministic approaches.

4. Consider developing and implementing training to address staffing changes, continuous staff development, and to bridge the gap between PRA and deterministic backgrounds.

5. Develop a PRA strengths and limitations course and establish requirements for taking the course.

6. Consider enhancing the current PRA Training program to explicitly address the relationship of deterministic, PRA and risk-informed practices. In addition this training should consider uncertainties and scope as noted above. Should also consider adapting some courses to video/electronic training media so that they can be offered more frequently.

APPENDICES

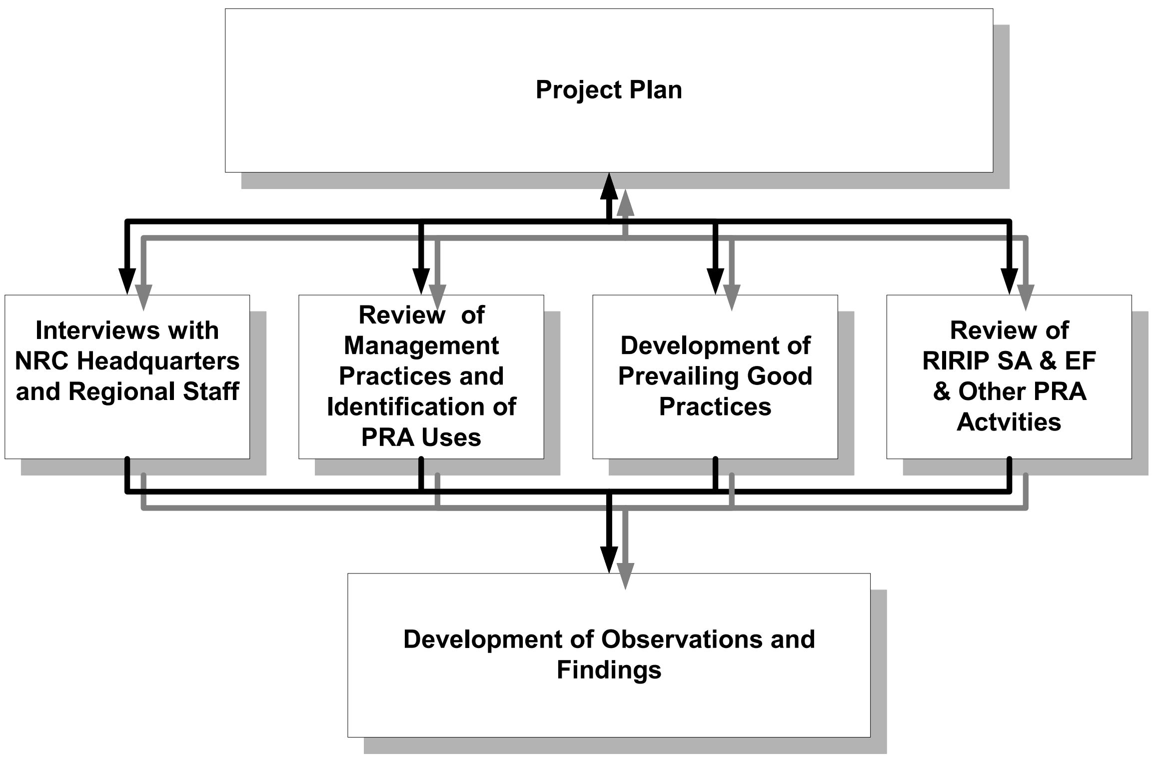
Appendix A - Scope and Methodology of Evaluation

A.1 Introduction

This appendix describes the approach used to conduct this evaluation and specific activities that were performed, namely:

- Development of a Project Plan,
- Interviews with NRC Headquarters and Regional Staff,
- Review of Management Practices and Identification of PRA Uses,
- Development of Prevailing Good Practices,
- Review of Risk Informed Regulation Implementation Plan (RIRIP) and Other PRA Activities, and
- Development of Observations and Findings.

The relationship of these activities is shown in the figure below.



Each of these activities is discussed in the following sections.

A.2 Project Plan

A project plan was prepared to define the evaluation activities as well as the overall project conduct. It included the approach and methodology for the evaluation including the plan for conducting the fieldwork, document reviews and application reviews, as well as the selection criteria for the application reviews.

A.3 Interviews

Interviews were conducted with NRC staff at headquarters and at each of the regional offices.

- NRC headquarters – 23 interviews where the incumbent of the position selected for interview (or their designee) participated and in some cases additional staff members.
- Interviews at NRC regions – 33 interviews including the Regional Administrators, the Division of Reactor Safety and Division Reactor Programs directors (or their designees), and at least one Senior Reactor Analyst (SRA) in each region.

The interviews were conducted to accomplish the following:

1. Inform agency staff of the objectives, scope, and approach of the evaluation,
2. Gain personal input on the use of PRA within the agency, including successes, opportunities, problems, and challenges,
3. Gain personal input on programs, processes, and documentation which would enable the evaluation team to complete the project,
4. Gain input to support the management oversight element of the evaluation, and
5. Identify additional NRC staff with whom discussions would be meaningful.

Follow-up discussions were conducted as appropriate, based on reviews of technical and programmatic documents.

A.4 Review of Management Practices and Identification of PRA Uses

Management practices related to PRA application and identification of PRA uses included the review of a large number of supporting documents as well as information obtained during the interviews discussed above. The information reviewed was organized into the following categories:

- Policy,
- Plans, Regulatory Guides and Standards,
- Specific documents related to Senior Reactor Analysts,
- Inspections, Inspection Procedures / Manual / Evaluations / Assessments, and
- Training Programs.

A.5 Development of Prevailing Good Practices

The prevailing good practices developed for this project characterize the prevailing good practices in PRA as of 2005. Prevailing good practices were defined or characterized as the generally accepted practices for conducting, reviewing and documenting PRA. The scope of the prevailing good practices documented included Level 1, 2, and 3 PRA, external events (fire, seismic and other), shutdown and low power PRA, and PRA Applications. Available guidance for PRA development and specific applications of PRA was also established. See appendix B for additional information on prevailing good practices.

A.6 Review of RIRIP SA & EF and Other PRA Activities

As part of the evaluation, risk informed application categories for more detailed investigation were selected from the RIRIP using a ranking scheme developed to focus on the applications with the highest significance and use. Based upon the information obtained from the interviews and from the review of management practices and identification of PRA uses, candidate safety initiatives and activities (SAs) and effectiveness initiatives and activities (EFs) for evaluation were further refined. The candidate SA and EF areas were screened on the basis of information availability, frequency of application, significance of application, level of difficulty, length of usage, and reliance on guidance. The SAs, EFs and other PRA uses that the project team identified for more detailed evaluation are shown in Table A-1 below. In addition to the selected SA and EF activities, the project selected "Other PRA Applications" as noted in the table.

Table A-1 List of Risk-Informed Regulation Implementation Plan Safety Initiatives and Activities & Effectiveness Initiatives and Activities and Other PRA Activities Reviews
RIRIP Reference SA-1: Maintain a RI Assessment Process for determining NRC Actions based on Performance Indicator and Inspection Implementation
Task 1 – Annual Status Report on ROP Implementation Task 2 – Effectiveness of Engineering Design Inspections Task 3 – Sample SDP Notebook, Revision 2 Task 4 – SDP Phase 3 Evaluation Task 5 – Sample of Implementation of an Inspection Procedure where PRA is considered
RIRIP Reference SA-5: Accident Sequence Precursor Analysis Program
Task 6 – Annual SECY Report on status of ASP and SPAR model Development
RIRIP Reference SA-10: Develop risk informed improvement to the standard technical specifications
Task 7 – Technical Specification Amendment Request
RIRIP Reference SA-11: Fire Protection for Nuclear Power Plants
Task 8 – License Amendment related to fire (ML052310005)
RIRIP Reference SA-14: Evaluation of Loss of Offsite Power (LOOP) Events and Station Blackout Risk
Task 9 – Evaluation of loss of offsite power (LOOP) event and station blackout (SBO) using SPAR model
RIRIP Reference EF-1: Creating a Risk-Informed Environment
Task 10 – Management actions and plans related to a Risk-Informed Environment
RIRIP Reference EF-2: Develop standards for the application of risk informed, performance based regulation in conjunction with national standards committees
Task 11 – NRC Regulatory Guides and Industry Standards
RIRIP Reference EF-3: Develop and maintain analytical tools for staff risk applications
Task 12 – SAPHIRE and GEM Tools
RIRIP Reference EF-21: SPAR Model Development Program (formerly SA-6)
Task 13 – SPAR models in ASP Task 14 – SPAR Model Development Program - Revision process and guidelines for Revision 3P SPAR Models Task 15 – Quality assurance guidelines for SPAR Models
OTHER APPLICATIONS BEYOND THOSE DESCRIBED IN RIRIP

Table A-1 **List of Risk-Informed Regulation Implementation Plan Safety Initiatives and Activities & Effectiveness Initiatives and Activities and Other PRA Activities Reviews**
Task 16 – Use of PRA for evaluation of Technical Specification Allowed Outage Time Changes
Task 17 – Licensee incident evaluation through ASP Evaluation

A.7 Development of Observations and Findings

Evaluation findings and observations were developed from the information obtained in the interviews, document reviews, and application evaluations and consideration of the prevailing good practices.

A finding is defined as a nonconformance, disclosed during the course of an evaluation, which requires written response indicating a corrective action plan and a schedule for implementation.

An observation is defined as an isolated/minor departure from requirements disclosed during the course of an evaluation which, if not addressed could lead to deficiencies or nonconformances in the future. In addition, observations are provided which are either positive attributes or areas where improvement should be considered.

Appendix B - Summary of PRA Prevailing Good Practices

B.1 Introduction

This appendix summarizes the prevailing good practices in PRA as of 2005. A document on prevailing good practices for PRA was developed as part of this project in order to support the evaluation. Prevailing good practices are defined or characterized as the generally accepted practices for conducting, reviewing and documenting PRA. The scope of the prevailing good practices includes Level 1, 2, and 3 PRA[10], external events (fire, seismic and other), shutdown and low power PRA, and PRA Applications. Available guidance for PRA development and specific applications of PRA is also provided.

The PRA prevailing good practices are primarily based upon the ASME "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications", ASME RA-S-2002 and its addenda, Regulatory Guide 1.200 for Trial Use, "An approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results For Risk-Informed Activities", and NEI 00-02, "Industry PRA Peer Review Process and Guidelines".

PRA has been used within the commercial nuclear power area for about 30 years. During this time period, methods, data and specific applications have been documented by NRC, vendors, consultants, licensees, national laboratories, and other U.S. and International organizations. The prevailing good practices in methods and data have changed with time.

No single document, or collection of documents, provides agreed upon prevailing good practices for every past or future PRA development or application. Rather there are multiple documents that have been developed over several years that serve to describe the prevailing good practices. The fundamental approach to addressing quality has been based on the following process:

- Using generally accepted methods and data or developing methods and data as deemed appropriate,
- Using qualified analysts,
- Subjecting the analysis to appropriate review, and
- Resolving review comments

To improve quality and the efficiency in preparing and reviewing PRAs and PRA applications, several organizations have developed, and are developing, standards and guidance. The major, recent or ongoing, documents that address PRA quality include:

- ***SECY-00-0162, July 28, 2000***, "Addressing PRA Quality in Risk-Informed Activities," (which provides the NRC approach to working with Industry to develop standards and provides minimum attributes and characteristics for a technically acceptable PRA).

[10] Level 1 PRA estimates the CDF (given an event that challenges plant operation occurs). Level 2 PRA estimates the containment failure and radionuclide release frequencies (given a core damage state occurs). Level 3 PRA estimates the offsite consequences from a release, e.g., early and latent cancer fatalities (given a radionuclide release occurs).

- ***SECY-04-0118, July 13, 2004***, "Plan for the implementation of the Commission's Phased Approach to Probabilistic Risk Assessment Quality," (which included a discussion of the plans for a three (3) phase approach to PRA quality).
- ***Numerous Regulatory Guides - 1.174, 1.175, 1.176, and 1.177***- (for changes to the license basis; and in the case of NRC's Inspection program, Inspection Manual Chapters, address specific application areas).
- ***Regulatory Guide 1.200 (for trial use), February 2004,*** "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." RG 1.200 addresses internal and external events for level 1 and level 2. (This RG, issued in February 2004, which is for trial use, also endorses the ASME standard with clarifications. Future revisions will address additional PRA standards as they are issued by the national consensus standards organizations.)
- ***ASME RA-S-2002 with addenda, December 2005 "***Standard For Probabilistic Risk Assessment for Nuclear Power Plant Applications***,"*** (The standard addresses Level 1 Internal Events PRA, Internal Flooding, and Large Early Release Frequency analysis (limited Level 2 PRA). The ASME standard does not address internal fires or other external hazards.)
- ***ANS Standard for External Events, ANSI/ANS-58.21-2003*** "American National Standard External-Events PRA Methodology" (This standard addresses external hazards. NRC is expected to endorse, possibly with clarifications, in 2006 or 2007.)
- ***ANS Standard for Fires*** (An internal fire PRA standard is under development by ANS, and is expected to be available in 2006. NUREG/CR-6850, Volumes 1 and 2 "EPRI/NRC-RES Fire PRA Methodology for Nuclear Power Facilities" was issued in 2005 and provides guidelines for performing an internal fire PRA.)
- ***ANS Standard for LP/SD*** (A Low Power/Shutdown (LP/SD) Standard should be completed in 2006/2007.)
- ***ANS Activity for Level 2 and Level 3*** (Development of Level 2 and Level 3 Standards are under consideration by ANS.)
- Numerous Topical Reports

B.2 Evaluation Use of Prevailing Good Practices

Prevailing good practices were used to support the evaluation of NRC's Use of PRA. Guidelines for using prevailing good practices in this evaluation were established for 3 key areas:

- PRA development and application,
- PRA configuration control, and
- PRA review.

B.3 Prevailing Good Practices

This section summarizes the prevailing good practices in PRA that were completed for all tasks of a Level I to III PRA, including internal and external events, and including initiators from shutdown and low power. The following sections summarize the prevailing good practices for PRA Scope, PRA Development and PRA Applications.

B.3.1 PRA SCOPE

The factors that affect the scope of a PRA include Endstates, Levels of PRA, Initiating Events, Outage Types, and Mission Time. The specific treatment of each these factors in the PRA is described in the table below, that includes an assessment of the state-of-the-art in PRA for a particular factor, and then characterizes the current prevailing good practice.

Table B-1
Prevailing Good Practices PRA Scope

PRA Scope Factor	PRA Prevailing Good Practice
Endstates	The state-of-the-art PRA models: ➢ All plant operational states ➢ Reactor trip as an undesired event ➢ Boiling for the Reactor Coolant System (RCS) in Cold Shutdown and for the Spent Fuel Pool ➢ Core damage for all plant operational states. The prevailing good practice is to address Internal events at power, and address the remaining scope using either PRA or deterministic/qualitative assessments as needed to address the specific topic.
Levels of PRA	A state-of-the art PRA would address Level 1, Level 2 and Level 3. The prevailing good practice is to address LERF for internal events and address a broader treatment of Level 2, and Level 3 only as needed (e.g., for Severe Accident Mitigation Alternatives and Integrated Leak Rate Testing applications).
Initiating Events	The state-of-the-art PRA models internal, spatial, and external events explicitly. Many state-of-the-art PRAs do not model initiating events involving fuel elements outside of the active core. For example, initiating events involving the spent fuel pool, or events involving the movement and transportation of fuel are not modeled. The prevailing good practice is to model internal events explicitly and the other events as needed either with PRA or qualitatively.
Outage Types	The state-of-the-art shutdown PRA models refueling outages, planned, and generally forced outages. These outage types cover nearly all of the outages expected to be encountered over the life cycle of a plant. Outages for steam generator replacement, single loop operations, or a containment pressure test are examples of potential exceptions that a state-of-the-art PRA would not have in its baseline modeling but which could be adapted to model such situations. The prevailing good practice varies here. The typical practice is to address outages qualitatively.
Mission Time	A mission time of 24 hours following the occurrence of an initiating event is typically modeled in the state-of-the-art PRA. Beyond twenty-four hours, the plant can accomplish a wide variety of recovery actions or repair equipment following most initiating events, such that modeling the accident progression of events beyond 24 hours is generally probabilistically insignificant. The state-of-the-art for some external events is 72 hours to reflect the requirement for extended reliability of mitigating equipment following an initiator such as a seismic event, tornado, or external flood that may isolate the plant for more than a day. This is consistent between the Full Power and Shutdown PRAs. The prevailing good practice is consistent with the state-of-the-art.
Other	In general, detailed human errors of commission analyses modeling error mechanisms and error producing conditions are not included in the state-of-the-art PRA. However, errors of commission that have caused initiating events are often explicitly modeled. The prevailing good practice is consistent with the state-of-the-art.

B.3.2 PRA Development

The prevailing good practice for each aspect of PRA development is summarized in Table B-2 below, along with the prevailing good practice references for each area.

Table B-2
Summary of PRA Prevailing Good Practice
For PRA Development

PRA Development Area	Prevailing Good Practice References (see Table B-4)
Internal Events PRAs	
Initiating Events Analysis	1,2
Accident Sequence Delineation	1,2
Success Criteria/Thermal Hydraulic Analysis	1.2
Systems Analysis	1,2
Human Reliability Analysis,	1,2
Data Analysis	1,2
Internal Flooding	1,2
Quantification	1,2
Level 2 PRA	1,2
Level 3 PRA	No Standard; Numerous NUREGs
Low Power and Shutdown PRA	1,5
External Events PRA	
Seismic	3
Fire Risk Analysis	4
Other External Events	3,18,19

B.3.3 PRA Applications

The prevailing good practice for PRA Applications is summarized in Table B-3 below, along with the prevailing good practice references for each area

Table B-3
Summary of Prevailing Good Practices
by PRA Application Areas

PRA Application Area	Description	References (see Table B-4)	Comments
Operational Uses			
Maintenance Rule (10CFR50.65)	(a)(4), for configuration control, establishes requirement to assess and manage configuration risk. Scope of SSCs may be limited based on risk-informed evaluation process.	12	All Plants must implement. NRC oversees implementation (inspection and enforcement). Utilities are increasing use of risk monitors and updating PRAs.
Plant Enhancements	Use of PRA to reduce risk by implementing design, operational, and maintenance changes.	20, 21	Ongoing program at utilities and NRC based on operating experience and new information (such as new insights from PRA updates).
Plant Modifications	Use of the PRA to evaluate the risk impact of proposed changes.	6	PRA is routinely used in addition to other plant change processes to assess the impact of plant changes.
Oversight (Industry-wide)			
NRC Accident Sequence Precursor Program	Ongoing program to assess the significance of events will continue.	Not applicable	Ongoing Program. Institute of Nuclear Power Operations and licensees also address.
NRC Plant Reliability Studies	NRC continues to review industry-wide performance, including initiating events, component and system reliability, and common cause failure evaluations.	Not applicable	Ongoing Program. Institute of Nuclear Power Operations also addresses similar topics.

Table B-3
Summary of Prevailing Good Practices
by PRA Application Areas

PRA Application Area	Description	References (see Table B-4)	Comments
Licensing			
Changes to the Licensing Basis-General	Use of PRA findings and risk insights in support of licensee requests to change a plant's licensing basis, as in requests for license amendments and technical specification changes.	6	Specific Applications are noted below. RG 1.174 and other application-specific Regulatory Guides are addressed when applying for a change, as appropriate.
NRC Requests for Risk Information for Licensing Actions	NRC can request risk information for licensing action requests, even if the request meets all existing requirements, and did not use risk information as a supporting basis.	6, 7, 20	Implemented by NRC as appropriate.
In-Service Inspection	NRC has approved two methods (Westinghouse Owners Group and Electric Power Research Institute) for ASME Section XI weld exams.	8	Most U.S. plants have implemented. Future initiatives could pursue further reduction in Section XI scope with no significant risk impact.
In-Service Testing	NRC has approved risk-informed inservice testing approach for pump and valve test interval optimization.	9	Only a few plants have implemented.

Table B-3
Summary of Prevailing Good Practices by PRA Application Areas

PRA Application Area	Description	References (see Table B-4)	Comments
Technical Specifications	PRA application has supported many individual allowed outage time (AOT) extensions. Several risk informed initiatives are underway addressing end states, mode restraints, 3.0.3, missed surveillances, out of service times, definition of "operability".	10	Many, if not most, plants for selected AOT extensions. Pilot plants for new initiatives.
Graded Quality Assurance	Grade Quality Assurance Program implementation on the basis of risk significance.	11	South Texas project received approval from NRC. Mostly incorporated into 10CFR Part 69.
Control Room Habitability	Apply PRA and Risk-informed approaches to support resolution of toxic gas issues related to control room monitoring and in-leakage.	18, 19	Some plants have addressed toxic gas releases using assessments that establish the frequency of loss of control room habitability to be below 1E-6 per year. A few plants have also included an assessment of the conditional probability of core damage to demonstrate an acceptably low frequency.
Appendix J	Change requirements for testing and/or allowable leakage rates.	13, 14, 15, 16, 17	Many plants have implemented Option B, II.B to Appendix J since 1994.
Oversight (Licensee)			

Table B-3
Summary of Prevailing Good Practices
by PRA Application Areas

PRA Application Area	Description	References (see Table B-4)	Comments
ROP	Revised ROP has been implemented.	Not applicable	Applied to all U.S. Plants. NRC and Industry are implementing alternative performance indicators to refine the current process and incorporate lessons learned (MSPI).
Notices of Enforcement Discretion	Use of PRA to support justification of continued operation (JCO) when explicit requirements, such as included in Technical Specifications, can not be demonstrated.	Not applicable	All U.S. plants. Ongoing as appropriate.
NRC Inspections	Use of PRA and risk Insights to improve the focus and effectiveness of inspections.	Not applicable	Applied to all U.S. Plants. Continuous improvement planned by NRC.
Training for Operators and Technical Staffs	Training to improve staff understanding of PRA and plant features to support improvement in risk management.	Not applicable	Ongoing as appropriate.
Rulemaking			
Part 50 – Regulatory Treatment (Option 2)	Rulemaking plan proposes new 10 CFR 50.69 to define the scope of SSCs subject to NRC "special treatment" regulations. Treatment would be function of risk significance and existing safety classification. Expected that treatment would be adjusted for many SSCs.	Not applicable	Guideline for risk categorization and definition of treatment under review by NRC. Owners Group Pilot Projects underway or planned. Draft Regulatory Guide, 1.201 issued in January 2006.

Table B-3
Summary of Prevailing Good Practices by PRA Application Areas

PRA Application Area	Description	References (see Table B-4)	Comments
Part 50 – Risk-Informing Technical Requirements (Option 3)	Design bases would be changed to incorporate risk-insights and operating experience. The pilot regulation for Option 3 was §50.44. §50.46, specifically the large-break loss-of-coolant accident (LOCA) requirement, is in rule making.	Not applicable	San Onofre was the pilot plant for 50.44, and received approval in 2000. Westinghouse Owners' Group is the industry lead in developing the basis for amending the large-break LOCA requirement. Other owners' groups are assessing the benefit to their plants. The schedule for implementing risk-informed improvements to other regulations will be based on the §50.46 improvements.

Table B-4
Prevailing Good Practice References for PRA Applications Listed in Table B-2 and B-3

Reference Number in Tables B3 & B4	Reference Description
1	Regulatory Guide 1.200 (for trial use), February 2004, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities Regulatory Guide 1.200 addresses internal and external events for level 1 and level 2. (This Regulatory Guide, issued in February 2004, which is for trial use, also endorses the ASME standard with clarifications. Future revisions will address additional PRA standards as they are issued by the national consensus standards organizations.)
2	ASME Standard (The Standard for an internal events at power PRA is ASME RA-S-2002 "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" with Addenda ASME RA-Sb-2005. The ASME standard contains criteria for a Level 1 Internal Events PRA, Internal Flooding, and Large Early Release Frequency analysis (limited Level 2 PRA). The ASME standard does not address internal fires or other external hazards.)
3	ANS Standard for External Events, ANSI/ANS-58.21-2003 "American National Standard External-Events PRA Methodology" (which contains guidance for PRA studies of other external hazards. NRC is expected to endorse, possibly with clarifications, ANSI/ANS-58.21-2003 in 2006.)
4	ANS Standard for Fires (An internal fire PRA standard is under development by ANS and is expected to be available in 2006. NUREG/CR-6850, Volumes 1 and 2 "EPRI/NRC-RES Fire PRA Methodology for Nuclear Power Facilities" was issued and provides guidelines in performing an internal fire PRA.)
5	ANS/ASME Standard for LP/SD (whereby a Low Power/Shutdown Standard should be completed in 2006.)
6	Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant-Specific Changes to the Licensing Basis."
7	Standard Review Plan Chapter 19, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance."
8	Regulatory Guide 1.178, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping."
9	Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing."
10	Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications."
11	Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance."
12	NUMARC 93-01.
13	Integrated Leak Rate Test Interval – Additional Information," Nuclear Energy Institute, November 30, 2001
14	NEI 94-01, "Industry Guideline for Implementing Performance-Based Option of 10CFR Part 50, Appendix J, July 26, 1995, Revision 0.
15	"Interim Guidance for Performing Risk Impact Assessments in Support of One-Time Extensions for Containment Integrated Leakage Rate Test Surveillance Intervals", Rev. 4, EPRI, November 2001.
16	EPRI TR-104285, "Risk Assessment of Revised Containment Leak Rate Testing Intervals," August 1994.
17	NUREG-1493, "Performance-Based Containment Leak-Test Program, July 1995".
18	Standard Review Plan; Sections 2.2.1, 2.2.2, 2.2.3, and 6.4, NUREG-0800.

Table B-4 Prevailing Good Practice References for PRA Applications Listed in Table B-2 and B-3	
Reference Number in Tables B3 & B4	**Reference Description**
19	Assumptions for Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release; Regulatory Guide 1.78, U.S. Atomic Energy Commission, June 1974.
20	Backfit Rule (10CFR50.109).
21	NRC ranking of Safety Issues, such as provided in NUREG-0933.