POLICY ISSUE
(Notation Vote)

October 11, 1996 SECY-96-218

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: QUARTERLY STATUS UPDATE FOR THE PROBABILISTIC RISK ASSESSMENT (PRA) IMPLEMENTATION PLAN, INCLUDING A DISCUSSION OF FOUR EMERGING POLICY ISSUES ASSOCIATED WITH RISK-INFORMED PERFORMANCE-BASED REGULATION

PURPOSE:

To provide a quarterly update on the progress of activities in the PRA Implementation Plan, including the development of risk-informed standards and guidance, and to provide the supplemental information requested in the May 15, 1996, Staff Requirements Memorandum (SRM), including a discussion of the four emerging policy issues associated with risk-informed, performance-based regulation.

BACKGROUND:

In a memorandum dated January 3, 1996, from the Executive Director for Operations to Chairman Jackson, the staff stated that it would provide quarterly updates on the status of developing risk-informed standards and guidance. Previous updates on the status of activities in the PRA Implementation Plan, including the status of developing risk-informed standards and guidance, were provided to the Commission on March 26 and June 20, 1996.

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In its SRM dated May 15, 1996, the Commission requested that the staff develop a policy paper, with recommendations, addressing the resolution of the four emerging policy issues identified in the March 26, 1996, quarterly status update. In the May 15, 1996, SRM, the Commission also requested that the staff provide an update on the implementation and use of subsidiary safety goal objectives and clarify how the staff intends to address uncertainty in the implementation of risk-informed and performance-based regulation.

The May 15 SRM also encouraged the staff to consider the use of expert judgement such as being applied in the high level waste area, as a guide for implementing the expert panel process being used for some risk-informed licensee applications. The Office of Nuclear Regulatory Research (RES) and Office of Nuclear Reactor Regulation (NRR) staffs have been following this work and are continuing to keep track of the NMSS development effort in high level waste management. All applicable information will be considered as a source of guidance in the development of Regulatory Guides and the Standard Review Plan sections for risk-informed applications.

DISCUSSION:

This Commission paper forwards: (1) the quarterly status update to the agency's PRA Implementation Plan; (2) the staff's recommendations concerning the four emerging policy issues identified in the March 26, 1996, PRA Implementation Plan status update; and (3) a list of technical issues that the staff is continuing to resolve during the development of risk-informed Standard Review Plans and Regulatory Guides.

The staff has updated the status of activities in the agency's PRA Implementation Plan in Attachment 1. The update includes a new activity that will address the Commission request in its May 21, 1996, SRM, that the staff track the regulatory uses of the IPE/IPEEE results and consider linking IPE/IPEEE databases together in a single, integrated, coherent program.

The staff recommendations concerning the four policy issues are contained in Attachment 2. Attachment 2 also contains the supplemental information requested by the Commission in its May 15, 1996, SRM concerning (1) implementation and use of subsidiary safety goal objectives and (2) uncertainty in the implementation of risk-informed and performance-based regulation. To meet the aggressive schedule for completing risk-informed standards and guidance, the staff continues to review pilot licensee risk-informed programs and develop Regulatory Guides and Standard Review Plans consistent with the staff's proposed recommendations on the policy issues.

Attachment 3 contains a summary list of key technical and process issues identified to date in the development of the Regulatory Guides (RGs) and Standard Review Plans (SRPs) and through the risk-informed pilot applications. The staff is working to resolve these issues and will propose its resolutions of these issues in the draft RGs and SRPs. A related issue in developing these Regulatory Guides and Standard Review Plans is the importance of the plant's current licensing basis. To proceed efficiently toward more risk-informed regulatory approaches, licensees and the staff must ensure that the plant's

current licensing basis and actual operating condition and practices continue to be properly reflected in the risk estimates using the plant PRA model. Otherwise, the risk assessment may provide inaccurate or misleading information that will need careful scrutiny before use in any regulatory decision-making process.

COORDINATION:

This paper was developed jointly by the Offices of Nuclear Reactor Regulation (NRR), Nuclear Regulatory Research (RES), Analysis and Evaluation of Operational Data (AEOD), and Nuclear Material Safety and Safeguards (NMSS).

The staff has briefed the Advisory Committee on Reactor Safeguards (ACRS) and its PRA subcommittee on the risk-informed policy issues, technical issues, and pilot applications. In its August 15, 1996, letter to the Chairman, the ACRS provided its views on selected issues related to risk-informed, performance-based regulation.

OGC has no legal objection.

RECOMMENDATIONS:

The staff recommends that the Commission:

(1) Agree to the staff's use of the recommended options on the four policy issues (as discussed in Attachment 2) in the continuing development of the Regulatory Guides and Standard Review Plans.

(2) Solicit comment on the staff's recommendations as part of the public comment process on the Regulatory Guides and Standard Review Plans (this is planned for January 1997).

(3) Note that the staff is working on the list of technical and process issues (Attachment 3) and will propose resolutions to these issues in the draft Regulatory Guides and Standard Review Plans.

(4) Note that the staff will continue to interact with risk-informed pilot licensees, industry representatives, ACRS, and the public regarding the increased use of risk insights in our regulatory processes.

James M. Taylor
Executive Director
for Operations

Attachments:
As stated

ATTACHMENT 1

STATUS UPDATE OF THE AGENCY-WIDE IMPLEMENTATION PLAN
FOR PROBABILISTIC RISK ASSESSMENT (PRA)
(FROM JUNE 1, 1996 TO AUGUST 31, 1996)

SUMMARY OF SIGNIFICANT PROGRESS

(1) Regulatory Guide (RG) and Standard Review Plan (SRP) Development (Tasks 1.1 and 2.1)

The draft broad-scope general RG and the draft application-specific RGs for Inservice Testing (IST), Graded Quality Assurance(GQA), and Technical Specifications (TS) are currently under inter-office review. The development of the draft RG for Inservice Inspection (ISI) is continuing. The staff has completed its review of the draft Nuclear Energy Institute (NEI) "Industry Guideline for Risk-Based Inservice Inspection" including the Westinghouse Owners Group methodology and is preparing to issue its comments and request for additional information to the industry.

The initial draft broad-scope general SRP and the initial application-specific draft SRP for ISI are under staff review. The draft SRP for IST has had several revisions and is still undergoing staff review. The development of the draft SRPs for GQA and TS is continuing. The significant amount of effort required by key staff members associated with the development of RGs and SRPs and the delays from some pilot licensees have contributed to some delays in the progress on pilot applications.

During the development of the RGs and SRPs, and through the risk-informed pilot applications, the staff identified a number of key technical and process issues related to risk-informed regulation. The PRA Coordination Committee (representatives from NRR, RES, AEOD, and NMSS at the Branch Chief level) has met with each of the RG/SRP development and pilot teams to discuss and review the list of key technical and process issues generated by the staff (Attachment 3). The staff is focusing its attention on these key issues during the pilot applications and the RG/SRP development. Resolution to these issues will be included in the final version of the risk-informed RGs and SRPs, as appropriate.

The staff has benefited from meetings with the ACRS and its PRA subcommittee to discuss technical and policy issues related to risk-informed, performance-based regulation. This dialog will continue during the RG and SRP development.

(2) Pilot Applications (Task 1.2)

The licensees' submittals for the risk-informed IST pilots (Comanche Peak and Palo Verde) have been very useful in assisting the staff to identify key technical and process issues to be included in the RG and SRP development. However, additional information from the licensees is needed for the staff to complete its evaluation of the proposed risk-informed

IST program and make recommendations to the Commission. Accordingly, the scheduled target date for the staff recommendation to the Commission on implementing the risk-informed IST pilot has been postponed to March 1997.

For the risk-informed ISI pilots (ANO-2, Fitzpatrick and Surry), an initial submittal from Surry was received in June. The submittals from ANO-2 and Fitzpatrick are delayed until October, 1996. The staff has had several meetings with representatives from Surry, Westinghouse Owners Group and the American Society of Mechanical Engineers (ASME) to identify and discuss key technical and process issues.

The graded QA volunteer pilot licensees (South Texas, Palo Verde, and Grand Gulf) have articulated a number of criteria for evaluating relative safety significance of structures, systems, and components (SSCs), particularly for those that are not modeled in the PRA. The staff has observed portions of the pilot licensees' graded QA process and incorporated elements of the pilot methodologies having merit in the development of the risk-informed RG and SRP.

The staff received the technical specifications pilot licensees' [Combustion Engineering Owners Group (CEOG)] response to the second request for additional information (RAI) for the Low Pressure Safety Injection System (LPSI) and the safety injection tanks (SITs) on June 19, 1996. The staff is awaiting response to the third RAI from the lead pilot licensee (Arkansas Nuclear One, Unit 2). The staff's contractor has reviewed the responses received to date and drafted a technical evaluation report. This report will serve as the basis for the staff's safety evaluations for the LPSI and SIT changes.

The staff met with the CEOG on August 15, 1996, to discuss the status of the technical specifications pilot activities and additional risk-informed technical specifications improvements that the CEOG is planning to submit in the future. The staff informed the CEOG that it may decide to visit a third pilot site before finalizing its review of the LPSI and SIT changes.

(3) Training for Inspectors (Task 1.3)

The staff has identified inspector functions and the areas where PRA methods can be applied to inspection activities. A draft course outline and task objectives were developed and forwarded to the Technical Training Division requesting training course development for NRC inspectors, project managers and technical reviewers. This new course is intended to combine applicable portions of several existing PRA training courses and present the material in an applications-oriented training environment.

Although there is a Senior Reactor Analyst (SRA) turnover issue due to selection of several individuals to supervisory positions, the PRA course training and rotational assignments for the remaining SRAs are on schedule and the SRAs are expected to be certified early next year.

(4) IPE and IPEEE Reviews (Task 2.5)

The internal NRC review of the draft NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," is on schedule and will be transmitted to the Commission for information in October 1996, and issued for public comment in October, 1996. This NUREG provides perspectives gained from reviewing 75 IPE submittals covering 108 nuclear power plant units.

As documented in SECY-96-088, "Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research," the staff could not conclude, based on the licensees' submittals, that all the licensees met the intent of Generic Letter 88-20. In that Commission paper, the staff indicated that IPE reviews will be completed by December 1996. Due to delays in responses from several licensees to staff questions, the completion of approximately three IPE SERs may slip beyond December 1996.

(5) Trending and Statistical Analysis Procedures (Task 3.1)

During this period, the seventh and last report in a series of trending and statistical analysis methods reports was completed. These reports addressed several topics for trending and analysis of different types of data. This completes the milestone "Develop standard trending and statistical analysis procedures for identified areas for reliability and statistical applications" under Task 3.1.

(6) Reliability Data Rule (Task 3.5)

Following the June public meeting on the proposed rule for collecting reliability and availability data, comments were received on the rule and the proposed regulatory guide. Work continues on modifications to the regulatory guide, the regulatory analysis supporting the rule, and the response to comments on the rule and regulatory guide. Efforts to obtain the necessary data through a voluntary program are continuing in parallel with the rule making activities. The Institute for Nuclear Power Operation (INPO) has indicated a willingness to allow the staff access to the Safety System Performance Indicator (SSPI) raw data in order to evaluate its usefulness and determine whether any deficiencies noted by such an evaluation can be remedied in the context of a voluntary program. INPO has declined to provide such data on a continuing basis unless the NRC adopts the voluntary approach to obtaining data as opposed to the approach in the proposed rule and regulatory guide.

(7) Staff Training (Task 3.6)

The staff has completed development of a guidance document for agency managers to assist them in developing training and development programs for their staff in the PRA area. The document, NUREG/BR-0228, "Guidance for Professional Development of NRC Staff in Regulatory Risk Analysis," was issued to all agency mangers and contains recommended PRA training guidelines for use by NRC staff.

The staff has developed and completed a dry run for the "PRA for Technical Managers" course. This course has been designed to provide all levels of staff managers a basic understanding of PRA methods, strengths and limitations. Feedback from the dry run was favorable and is being used to finalize the training module.

A new PRA Level 2 course, "Accident Progression Analysis," has been developed. This three-day course addresses accident phenomenology under post-core damage conditions and discusses the PRA modeling technique for this severe accident regime. The staff is developing a new PRA Level 3 course, "Accident Consequence Analysis." This three-day course will address environmental transport of radionuclides and estimation of offsite consequences from core damage accidents.

REVISIONS TO THE EXISTING PRA IMPLEMENTATION PLAN

Key staff members are on the team to develop risk-informed RGs and SRPs, as well as the review of work on pilot applications. Since their effort has been heavily committed to the development of RGs and SRPs, combined with delays for some pilot licensees, the progress on the pilot application has been hampered and the schedules for completion of the pilot SERs have been extended as discussed in the following paragraphs.

Both risk-informed IST pilots' (Comanche Peak and Palo Verde) responses to staff questions were too general and did not provide a sufficient basis for the staff to reach a conclusion regarding the "acceptable level of quality and safety" afforded by the proposed risk-informed IST programs. Consequently, the staff does not anticipate having enough information on which to make a decision relative to the acceptability of the RI-IST programs proposed by the pilot plant licensees until early next year. Accordingly, the scheduled target date for staff recommendation on the risk-informed IST pilot application (Task 1.2) has been postponed to March 1997.

The staff's recommendation to the Commission regarding the risk-informed technical specification pilot (Task 1.2) has been delayed 3 months from the original schedule due to the delay in the response to the third RAI from the lead pilot licensee. The staff expects to have its recommendation to the Commission in December 1996.

The graded QA pilot (Task 1.2) has proceeded at a slower pace than originally anticipated due to several factors, namely: licensee resolution of staff comments are outstanding; licensee resources for implementation of risk-informed graded QA have not received high priority due to other plant needs; staff review efforts have taken longer than expected due to workload impacts and difficult technical issue resolution; and the licensees' linkage of graded QA risk ranking with other risk-informed application results. Consequently, the graded QA volunteer pilot effort completion date has been postponed 6 months to June 1997. The staff anticipates that lessons learned from the volunteer efforts will continue to be assimilated by the staff after draft regulatory guidance documents (SRP and RG) have been generated and incorporated in the final draft after the public comment period ends.

Although the pilot applications have experienced delays as summarized above, the staff still intends to meet the aggressive schedule for the development and issuance of draft risk-informed RGs and SRPs. The staff plans to issue draft RGs and SRPs for public comment. These draft RGs and SRPs will contain a number of policy and technical issues that need to be resolved following the public comment period.

Inspection Manual Chapter 9900 revisions which provide high level guidance on incorporation of risk insights into the reactor inspection program have been drafted and are currently under staff review (Task 1.3). The progress on providing more detailed PRA insights to the reactor inspection program has been delayed because of diversion of resources to other critical short term activities such as the Millstone Task Force and the Maintenance Rule baseline inspections.

Regarding applying risk insights in operator licensing (Task 1.4), the staff recommended in SECY-96-123, "Proposed Changes to the NRC Operator Licensing Program," that the revised operator licensing process be implemented on a voluntary basis with the issuance of Revision 8 of NUREG-1021 and that the Commission approve the staff's pursuit of rulemaking to require power reactor facility licensees to prepare the operator licensing examinations in accordance with NUREG-1021. In an SRM dated July 23, 1996, the Commission requested the staff to develop a detailed rulemaking plan to justify changes that may be necessary to 10 CFR Part 55 and directed the staff to address a number of issues regarding the proposed examination process. The Commission deferred making a decision on implementation of the revised examination process on an industry-wide basis until the rulemaking plan and the responses to the additional items are reviewed. Although, the staff has made the appropriate revisions to NUREG-1021, the NUREG will not be implemented until after the Commission approves the proposed new examination methodology.

In its Staff Requirements Memorandum of May 21, 1996, the Commission requested that the staff track the regulatory uses of the individual plant examination/individual plant examination, external events (IPE/IPEEE) results. The Commission also stated that consideration should be given to linking resulting IPE/IPEEE databases together in a single, integrated and coherent program. Task 1.10 has been expanded to monitor and track the regulatory use of the results from the IPE/IPEEE. An important aspect of this activity will be the tracking of cumulative risk changes from licensees' use of IPE/IPEEE results in regulatory applications.

AEOD has completed an initial draft report on performance of risk-important components (Task 3.1). Peer review comments (including concerns about the completeness of the Nuclear Power Reliability Data System [NPRDS] and assumptions used for estimating demands, especially for plant-specific evaluations) have resulted in a delay of this work while they are being resolved. AEOD has set a new target date of February 1997 to complete the report. The risk-important initiating event study was delayed due to resource limitations.

For the Accident Sequence Precursor (ASP) program (Task 3.2), the initial ASP models for low power and shutdown conditions have been received. However, due to other higher priority tasks, the staff is not expected to complete the review of these models until November 1996.

REVISED TASK TABLES

The attached task tables have been updated to reflect the progress and revisions to the PRA Implementation Plan from June 1 to August 31, 1996.

REVISED PRA IMPLEMENTATION PLAN
TASK TABLE (SEPTEMBER 1996)

1.0 REACTOR REGULATION

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.1 DEVELOP STANDARD REVIEW PLANS FOR RISK-INFORMED REGULATION	Standard review plans for NRC staff to use in risk-informed regulatory decision-making.	* Evaluate available industry guidance. * Develop a broad scope standard review plan (SRP) and a series of application specific standard review plan chapters that correspond to industry initiatives. * These SRPs will be consistent with the Regulatory Guides developed for the industry. * Issue draft SRP for public comment General IST ISI GQA TS * Issue final SRP General IST ISI GQA TS	 12/96 12/96 3/97 12/96 12/96 12/97 12/97 12/97 12/97 12/97	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.2 PILOT APPLICATION FOR RISK-INFORMED REGULATORY INITIATIVES	* Evaluate the PRA methodology and develop staff positions on emerging, risk-informed initiatives, including those associated with: 1. Motor operated valves. 2. IST requirements. 3. ISI requirements. 4. Graded quality assurance. 5. Maintenance Rule. 6. Technical specifications. 7. Other applications to be identified later.	* Interface with industry groups. * Evaluation of appropriate documentation (e.g., 10 CFR, SRP, Reg Guides, inspection procedures, and industry codes) to identify elements critical to achieving the intent of existing requirements. * Evaluation of industry proposals. * Evaluation of industry pilot program implementation. * As appropriate, complete pilot reviews and issue staff findings on regulatory requests.	1. 2/96C* 2. 3/97 3. 6/97 4. 6/97 5. 9/95C 6. 12/96	NRR
1.3 INSPECTIONS	* Provide guidance on the use of plant-specific and generic information from IPEs and other plant-specific PRAs.	* Develop IMC 9900 technical guidance on the use of PRAs in the power reactor inspection program. * Revise IMC 2515 Appendix C on the use of PRAs in the power reactor inspection program. * Propose guidance options for inspection procedures related to 50.59 evaluations and regular maintenance observations. * Review core inspection procedures and propose PRA guidance where needed.	12/96 6/97 10/96 6/97	NRR
	* Provide PRA training for inspectors. *Provide PRA training for Senior Reactor Analysts (SRA)	* Identify inspector functions which should utilize PRA methods, as input to AEOD/TTD for their development and refinement of PRA training for inspectors. * Develop consolidated/comprehensive2-3 week PRA for regulatory applications training course. * First course offering. * Conduct training for Maintenance Rule baseline inspections * Conduct training courses according to SRA training programs * Rotational assignments for SRAs to gain working experience	7/96C 12/96 12/96 8/96C 3/97 3/97	NRR NRR/ AEOD NRR/ AEOD NRR NRR/RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Continue to provide expertise in risk assessment to support regional inspection activities and to communicate inspection program guidance and examples of its implementation.	* Monitor the use of risk in inspection reports. * Develop new methodologies and communicate appropriate uses of risk insights to regional offices. * Update inspection procedures as needed. * Assist regional offices as needed. * Conduct Maintenance Rule baseline inspections	Ongoing 7/98	NRR
1.4 OPERATOR LICENSING	Monitor insights from HRAs and PRAs (including IPEs and IPEEEs) and operating experience to identify possible enhancements for inclusion in planned revisions to guidance for operator licensing activities (initial and requalification)	* Revise the Knowledge and Abilities (K/A) Catalogs (NUREGs 1122 and 1123) to incorporate operating experience and risk insights. * Revise the Examiner Standards (NUREG-1021), as needed, to reflect PRA insights.	8/95C 12/96	NRR NRR
1.5 EVENT ASSESSMENT	* Continue to conduct quantitative event assessments of reactor events while at-power and during low power and shutdown conditions.	* Continue to evaluate 50.72 events using ASP models.	Ongoing	NRR
	* Assess the desirability and feasibility of conducting quantitative risk assessments on non-power reactor events.	* Define the current use of risk analysis methods and insights in current event assessments. * Assess the feasibility of developing appropriate risk assessment models. * Develop recommendations on the feasibility and desirability of conducting quantitative risk assessments.	TBD	NRR
1.6 EVALUATE USE OF PRA IN RESOLUTION OF GENERIC ISSUES	* Audit the adequacy of licensee analyses in IPEs and IPEEEs to identify plant-specific applicability of generic issues closed out based on IPE and IPEEE programs.	* Identify generic safety issues to be audited. * Select plants to be audited for each issue. * Describe and discuss licensees' analyses supporting issue resolution. * Evaluate results to determine regulatory response; i.e., no action, additional audits, or regulatory action.	6/97	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.7 REGULATORY EFFECTIVENESS EVALUATION	* Assess the effectiveness of two major safety issue resolution efforts (i.e., SBO and ATWS rules) for reducing risk to public health and safety.	* Develop process/guidance for assessing regulatory effectiveness. * Apply method to assess reduction in risk. * Evaluate result, effectiveness of rules. * Propose modifications to resolution approaches, as needed. * Identify other issues for assessment if appropriate.	9/97	NRR & RES
1.8 ADVANCED REACTOR REVIEWS	* Continue staff reviews of PRAs for design certification applications.	* Continue to apply current staff review process.	Ongoing	NRR
	* Develop SRP to support review of PRAs for design certification reviews of evolutionary reactors (ABWR and System 80+).	* Develop draft SRP to tech staff for review and concurrence. * Finalize SRP.	6/98 12/99	NRR
	* Develop independent technical analyses and criteria for evaluating industry initiatives and petitions regarding simplification of Emergency Preparedness (EP) regulations.	* Reevaluate risk-based aspects of the technical bases for EP (NUREG-0396) using insights from NUREG-1150, the new source term information from NUREG-1465, and available plant design and PRA information for the passive and evolutionary reactor designs.	12/96	NRR & RES
1.9 ACCIDENT MANAGEMENT	* Develop generic and plant specific risk insights to support staff audits of utility accidents management (A/M) programs at selected plants.	* Perform an assessment of A/M-related information contained in IPE databases to develop generic insights into A/M strategies and capabilities and document it in IPE Insights Report. * Develop plant-specific A/M insights/information for selected plants to serve as a basis for assessing completeness of utility A/M program elements (e.g., severe accident training)	6/97 TBD	NRR & RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.10 EVALUATING IPE INSIGHTS TO DETERMINE NECESSARY FOLLOW-UP ACTIVITIES	* Use insights from the staff review of IPEs to identify potential safety, policy, and technical issues, to determine an appropriate course of action to resolve these potential issues, and to identify possible safety enhancements.	* Review the report "IPE Program: Perspectives on Reactor Safety and Plant Performance" and identify required staff and industry actions (if any).	12/97	NRR & RES
		* Audit licensee improvements that were credited in the IPEs to determine effectiveness of licensee actions to reduce risk.	TBD	
	* Determine appropriate approach for tracking the regulatory uses of IPE/IPEEE results.	* Define use for information, clarify "regulatory use", and assess the most effective methods for data collection.	12/97	NRR
		* If appropriate, develop approach for linking IPE/IPEEE data bases.	12/98	

*C=Complete

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.1 DEVELOP REGULATORY GUIDES	Regulatory Guides for industry to use in risk-informed regulation.	* Issue draft PRA Regulatory Guides for public comment. General IST ISI GQA TS * Issue final PRA Regulatory Guides. General IST ISI GQA TS	 12/96 12/96 3/97 12/96 12/96 12/97 12/97 12/97 12/97 12/97	RES
2.2 TECHNICAL SUPPORT	* Provide technical support to agency users of risk assessment in the form of support for risk-based regulation activities, technical reviews, issue risk assessments, statistical analyses, and develop guidance for agency uses of risk assessment.	* Continue to provide *ad hoc* technical support to agency PRA users. * Expand the database of PRA models available for staff use, expand the scope of available models to include external event and low power and shutdown accidents, and refine the tools needed to use these models, and continue maintenance and user support for SAPHIRE and MACCS computer codes. * Support agency efforts in reactor safety improvements in former Soviet Union countries.	Continuing Continuing Continuing	RES RES RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.3 SUPPORT FOR NRR STANDARD REACTOR PRA REVIEWS	* Modify 10 CFR 52 and develop guidance on the use of updated PRAs beyond design certification (as described in SECY 93-087).	* Develop draft guidance and rule. * Solicit public comment. * Finalize staff guidance and rule.	5/98 11/98 12/99	RES RES RES
2.4 METHODS DEVELOPMENT AND DEMONSTRATION	* Develop, demonstrate, maintain, and ensure the quality of methods for performing, reviewing, and using PRAs and related techniques for existing reactor designs.	* Develop and demonstrate methods for including aging effects in PRAs. * Develop and demonstrate methods for including human errors of commission in PRAs. * Develop and demonstrate methods to incorporate organizational performance into PRAs. * Develop and demonstrate risk assessment methods appropriate for application to medical and industrial licensee activities.	9/97 6/97 9/97 6/97	RES RES RES RES & NMSS
2.5 IPE AND IPEEE REVIEWS	* To evaluate IPE/IPEE submittals to obtain reasonable assurance that the licensee has adequately analyzed the plant design and operations to discover vulnerabilities; and to document the significant safety insights resulting from IPE/IPEEEs.	* Complete reviews of IPE submittals. * Complete reviews of IPEEE submittals. * Continue regional IPE presentations. * Issue IPE insights report for public comment. * Final IPE insights report * Issue interim IPEEE insights report * Issue draft final IPEEE insights report	12/96* 12/98 Ongoing 10/96 6/97 9/97 9/98	RES RES RES RES RES RES RES
2.6 GENERIC ISSUES PROGRAM	* To conduct generic safety issue management activities, including prioritization, resolution, and documentation, for issues relating to currently operating reactors, for advanced reactors as appropriate, and for development or revision of associated regulatory and standards instruments.	* Continue to prioritize and resolve generic issues.	Continuing	RES

* Approximately 3 SERs may slip beyond 12/96; staff is awaiting additional information from licensees

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office
3.1 RISK-BASED TRENDS AND PATTERNS ANALYSIS	* Use reactor operating experience data to assess the trends and patterns in equipment, systems, initiating events, human performance, and important accident sequence.	* Trend performance of risk-important components. * Trend performance of risk-important systems. * Trend frequency of risk-important initiating events. * Trend human performance for reliability characteristics.	2/97 Annual rpt-9/97 12/96 TBD	AEOD
	* Evaluate the effectiveness of licensee actions taken to resolve risk significant safety issues.	* Trend reactor operating experience associated with specific safety issues and assess risk implications as a measure of safety performance.	As needed	AEOD
	* Develop trending methods and special databases for use in AEOD trending activities and for PRA applications in other NRC offices.	* Develop standard trending and statistical analysis procedures for identified areas for reliability and statistical applications. * Develop special software and databases (e.g. common cause failure) for use in trending analyses and PRA studies.	Complete CCF-Complete Periodic updates	AEOD
3.2 ACCIDENT SEQUENCE PRECURSOR (ASP) PROGRAM	* Identify and rank risk significance of operational events.	* Screen and analyze LERs, AITs, IITs, and events identified from other sources to obtain ASP events. * Perform independent review of each ASP analyses. Licensees and NRC staff peer review of each analysis. * Complete quality assurance of Rev. 2 simplified plant specific models. * Complete feasibility study for low power and shutdown models. * Complete initial containment performance and consequence models.	Ongoing Annual report, Ongoing 3/97 11/96 Complete	AEOD AEOD RES RES RES
	* Provide supplemental information on plant specific performance.	* Share ASP analyses and insights with other NRC offices and Regions.	Annual rpt	AEOD

Regulatory Actvity	Objectives	Methods	Target Schedule	Lead Office
3.3 INDUSTRY RISK TRENDS	* Provide a measure of industry risk that is as complete as possible to determine whether risk is increasing, decreasing, or remaining constant over time.	* Develop program plan which integrates NRR, RES, and AEOD activities which use design and operating experience to assess the implied level of risk and how it is changing. * Implement program plan elements which will include plant-specific models and insights from IPEs, component and system reliability data, and other risk-important design and operational data in an integrated frame work to periodically evaluate industry trends.	Complete 8/97	AEOD
3.4 RISK-BASED PERFORMANCE INDICATORS	* Establish a comprehensive set of performance indicators and supplementary performance measures which are more closely related to risk and provide both early indication and confirmation of plant performance problems.	* Identify new or improved risk-based PIs which use component and system reliability models & human and organizational performance evaluation methods. * Develop and test candidate PIs/performance measures. * Implement risk-based PIs with Commission approval.	Complete 3/98 9/98	AEOD
3.5 COMPILE OPERATING EXPERIENCE DATA	* Compile operating experience information in database systems suitable for quantitative reliability and risk analysis applications. Information should be scrutable to the source at the event level to the extent practical and be sufficient for estimating reliability and availability parameters for NRC applications.	* Manage and maintain SCSS and the PI data base, provide oversight and access to NPRDS, obtain INPO's SSPI, compile IPE failure data, collect plant-specific reliability and availability data. * Develop, manage, and maintain agency databases for reliability/availability data (equipment performance, initiating events, CCF, ASP, and human performance data). * Revise reporting rules to better capture equipment reliability information. * Determine need to revise LER rule to eliminate unnecessary and less safety-significant reporting. * Determine need to revise reporting rules and to better capture ASP, CCF, and human performance events.	Ongoing Ongoing Proposed-Compl.-2/96 Final-10/97 4/97 6/98	AEOD

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
3.6 STAFF TRAINING	* Present PRA curriculum as presently scheduled for FY 1996	* Continue current contracts to present courses as scheduled. * Maintain current reactor technology courses that include PRA insights and applications. * Improve courses via feedback. * Review current PRA course material to ensure consistency with Appendix C.	Ongoing Ongoing Ongoing Complete	AEOD
	* Develop and present Appendix C training courses.	* Prepare course material based on Appendix C. * Present courses on Appendix C.	Complete Complete	RES and AEOD
	* Determine staff requirements for training, including analysis of knowledge and skills, needed by the NRC staff.	* Review JTAs performed to date. * Perform representative JTAs for staff positions (JTA Pilot Program). * Evaluate staff training requirements as identified in the PRA Implementation Plan and the Technical Training Needs Survey (Phase 2) and incorporate them into the training requirements analysis. * Analyze the results of the JTA Pilot Program and determine requirements for additional JTAs. * Complete JTAs for other staff positions as needed. * Solicit a review of the proposed training requirements. * Finalize the requirements.	Complete Complete Complete Ongoing Ongoing Ongoing Ongoing	AEOD
	* Revise current PRA curriculum and develop new training program to fulfill identified staff needs.	* Prepare new courses to meet identified needs. * Revise current PRA courses to meet identified needs. * Revise current reactor technology courses as necessary to include additional PRA insights and applications.	12/97 12/97 Complete 3/96	AEOD
	* Present revised PRA training curriculum.	* Establish contracts for presentation of new PRA curriculum. * Present revised reactor technology courses. * Improve courses based on feedback.	Ongoing Ongoing Ongoing	AEOD

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
4.1 Validate risk analysis methodology developed to assess most likely failure modes and human performance in the use of industrial and medical radiation devices.	* Validate risk analysis methodology developed to assess the relative profile of most likely contributors to misadministrations for the gamma stereotactic device (gamma knife).	* Hold a workshop consisting of experts in PRA and HRA to examine existing work and to provide recommendations for further methodological development. * Examine the use of Monte Carlo simulation and its application to relative risk profiling. * Examine the use of expert judgement in developing error rates and consequence measures.	8/94 Completed 9/95 Completed 9/95 Completed	NMSS
	* Continue the development of the relative risk methodology, with the addition of event tree modeling of the brachytherapy remote afterloader.	* Develop functionally based generic event trees.	TBD	RES/ NMSS
	* Extend the application of the methodology and its further development into additional devices, including teletherapy and the pulsed high dose rate afterloader.	*Develop generic risk approaches.	TBD	RES/ NMSS
4.2 Continue use of risk assessment of allowable radiation releases and doses associated with low-level radioactive waste and residual activity.	* Develop decision criteria to support regulatory decision making that incorporates both deterministic and risk-based engineering judgement.	* Conduct enhanced participatory rulemaking to establish radiological criteria for decommissioning nuclear sites; technical support for rulemaking including comprehensive risk based assessment of residual contamination. * Work with DOE and EPA to the extent practicable to develop common approaches, assumptions, and models for evaluating risks and alternative remediation methodologies. (Risk harmonization).	8/94 PR Complete Final Rule 6/96- 3/97 (Dependent on EPA) Ongoing	RES & NMSS
4.3 Develop guidance for the review of risk associated with waste repositories.	* Develop a Branch Technical Position on conducting a Performance Assessment of a LLW disposal facility.	* Solicit public comments * Publish final Branch Technical Position	1/97 8/97	NMSS & RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
5.1 REGULATION OF HIGH-LEVEL NUCLEAR WASTE	* Develop guidance for the NRC and CNWRA staffs in the use of PA to evaluate the safety of HLW programs.	* Assist the staff in pre-licensing activities and in license application reviews. * Develop a technical assessment capability in total-system and subsystem PA for use in licensing and pre-licensing reviews. * Combine specialized technical disciplines (earth sciences and engineering) with those of system modelers to improve methodology.	Ongoing	NMSS
	* Identify significant events, processes, and parameters affecting total system performance.	* Perform sensitivity studies of key technical issues using iterative performance assessment (IPA).	Ongoing	NMSS
	* Use PA and PSA methods, results and insights to evaluate proposed changes to regulations governing the potential repository at Yucca Mountain.	* Assist the staff to maintain and to refine the regulatory structure in 10 CFR Part 60 that pertains to PA. * Apply IPA analyses to advise EPA in its development of a Yucca Mountain regulation * Apply IPA analyses to conform 10 CFR 60 to EPA's regulations	Ongoing	NMSS
	* Continue PA activities during interactions with DOE during the pre-licensing phase of repository development, site characterization, and repository design.	* Provide guidance to the DOE on site characterization requirements, ongoing design work, and licensing issues important to the DOE's development of a complete and high-quality license application. * Compare results of NRC's iterative performance assessment to DOE's TSPA-95 to identify major differences/issues.	Ongoing	NMSS

ATTACHMENT 2

This attachment contains the supplemental information requested by the Commission in its Staff Requirements Memorandum dated May 15, 1996. This supplemental information includes 1) a discussion of the four emerging policy issues identified in the March 26, 1996, memorandum from the Executive Director for Operations to the Commission providing an update on the agency's Probabilistic Risk Assessment (PRA) Implementation Plan, 2) a discussion of the implementation and use of subsidiary safety goal objectives, and 3) a discussion of the staff's plans to address uncertainty in the implementation of risk-informed and performance-based regulation.

I. EMERGING POLICY ISSUES

In a memorandum dated March 26, 1996 from the EDO to the Commission, the staff identified the following four emerging policy issues:

- The role of performance-based regulation in the PRA Implementation Plan
- Plant-specific application of safety goals
- Risk neutral vs. increases in risk
- Implementation of changes to risk-informed IST and ISI requirements.

As requested by the Commission, each emerging policy issue is discussed below. The discussions briefly describe the issue, the alternatives, including the pros and cons, and provide the staff's recommendation. The staff has also considered the comments contained in the Advisory Committee on Reactor Safeguards letter of August 15, 1996, concerning risk-informed and performance-based regulation.

A. THE ROLE OF PERFORMANCE-BASED REGULATION IN THE PRA IMPLEMENTATION PLAN

In its Policy Statement "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622, August 16, 1995), the Commission affirmed that the use of PRA should be encouraged and that the scope of PRA applications in all nuclear regulatory matters should be expanded to the extent supported by the state-of-the-art in methods and data. The Commission's PRA Policy Statement and the PRA Implementation Plan continue to provide a necessary focus for the staff and industry to proceed toward more risk-informed regulatory approaches that enhance safety decision-making, improve staff efficiency, and/or reduce industry burden.

"Risk-informed" and "performance-based" are not necessarily synonymous terms, and the Commission's PRA Policy Statement does not explicitly discuss performance-based regulation. It is important for the staff and the industry to explore this regulatory concept with careful and deliberate thought. Most of the staff's experience with performance-based regulation has been gained through PRA pilot applications, implementation of the Maintenance Rule (10 CFR 50.65), and other rulemaking. For example, the recent rulemaking on 10 CFR Part 50, Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors" (60 FR 49495), implemented a performance-based option for leakage-rate testing for containments. In addition, several proposed and

ongoing rule changes (as described in the "Proposed Rulemaking Activity Plan," SECY-96-176) take a performance-based approach. The PRA Implementation Plan pilot applications for inservice testing of pumps and valves and inservice inspection are also partly performance-based, focussing on component and system performance. The staff continues to explore approaches that utilize performance assessment.[1]

After reviewing lessons-learned to date with risk-informed regulatory initiatives and after reviewing the performance-based elements proposed by the Nuclear Energy Institute (NEI), the staff has concluded that a risk-informed, performance-based regulatory approach should have at least four key elements: (1) there are measurable or calculable parameters to monitor plant and licensee performance, (2) objective criteria are established to assess performance based on a combination of risk insights, deterministic analysis, and performance history, (3) the licensee has flexibility to determine how to meet established performance criteria, and (4) failure to meet a performance criterion will not have an intolerable outcome.[2]

In some cases, performance-based regulatory approaches can be incorporated into risk-informed regulatory approaches. In other cases, performance-based regulatory approaches can be implemented without the explicit use of risk insights. The latter type of performance-based approach would involve objective performance criteria based on deterministic analysis, engineering judgment, and performance history.

The staff has identified three alternatives for addressing the issue of how performance-based regulation should be implemented.

Alternative 1: Implement performance-based regulation in the context of the current PRA Implementation Plan through the current process. That is, where practical, include performance-based strategies in the implementation of the risk-informed regulatory decision-making process.

PROS

This alternative has several advantages. First, it would allow staff to continue the current process, under the PRA Implementation Plan, for considering risk-informed, performance-based approaches on their own merits on a case-by-case basis. The PRA Implementation Plan is periodically updated to reflect the progress of planned activities, or to add new areas where the staff is pursuing risk-informed approaches.

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[1] These assessments of performance are not identical to and do not have the same regulatory roles as "performance assessments" of waste management facilities.

[2] For waste disposal, performance criteria are inherent in defining the acceptability of the overall system for disposal. For low-level waste, and perhaps high-level waste, dose (and thus risk) criteria are elements of the governing regulations. Thus, for waste disposal, the regulatory approach is both risk-based and performance-based and failure to meet the criteria would be noncompliance.

Second, the current process is responsive to numerous risk-informed industry initiatives in the power reactor area, where the potential benefits for reducing unnecessary industry burden, enhancing safety decision-making, and improving staff efficiency are readily apparent.

Third, under this alternative, risk-informed modification of rules and regulations to move toward increased performance-based regulation would be complementary to the PRA Implementation Plan activities. This complementary approach would promote regulatory coherence and help ensure that the legal and technical issues associated with performance-based approaches are resolved in the context of (and, where appropriate, integrated with) risk-informed regulatory approaches. Currently, performance-based strategies are considered in the implementation and monitoring step of the risk-informed decision-making process the staff is developing for reactor-related activities.

Finally, since this alternative is the current process, a significant change in resource allocation is not necessary to implement it. The resource and programmatic consequences are gradual and incremental.

CONS

The current process could be perceived as moving too slowly toward more performance-based regulatory approaches.

Alternative 2: Implement performance-based regulation as an explicit element of the PRA Implementation Plan by actively soliciting from industry a limited number of additional performance-based initiatives which are also suitable for risk-informed changes.

PROS

This alternative has two advantages. First, it would allow the staff and industry to gain additional experience on performance-based industry initiatives that may not necessarily be part of risk-informed initiatives.

Second, this approach would be responsive to industry initiatives for pursuing performance-based approaches. The transition to performance-based regulatory approaches would focus on areas supported by the industry.

CONS

Additional performance-based pilot reviews would divert staff resources from other regulatory activities and could cause delays in schedules or require additional resources.

Alternative 3: Implement performance-based regulation outside the context of the PRA Implementation Plan.

PROS

Under this alternative, the agency could move aggressively toward performance-based regulatory approaches by establishing a separate oversight program outside the oversight provided by the PRA Implementation Plan. This alternative would be parallel to, and perhaps independent of, risk-informed efforts. The agency could pursue performance-based approaches that are not explicitly risk-informed avoiding many of the risk-related technical issues.

CONS

Significant staff resources would be needed to support a concentrated effort to pursue performance-based approaches, to separately review the regulations and regulatory decision-making processes, and implement rulemaking or procedural changes. It is likely that these resources would have to be diverted from other ongoing or planned regulatory activities. This parallel approach might make it more difficult to integrate activities in areas where risk-informed and performance-based approaches are complementary.

Also, because it would be resource intensive, this alternative could also be the most costly to licensees, at least in the short term. Their participation in and support for such activities could depend on the extent to which they perceived near-term benefits.

STAFF RECOMMENDATION

The staff recommends Alternative 1.

With this approach, the staff plans to include performance-based strategies in the implementation of risk-informed regulatory decision-making processes to the extent that they relate to the activities in the PRA Implementation Plan. Because the staff is aware of a recent OIG audit focusing on peformance-based regulation, the staff will review the findings and recommendations contained in the audit report, after issuance, and inform the Commisison of any changes to the staff's recommendation.

In its letter of August 15, 1996, the ACRS stated that it "agree[d] with the staff that, where practical, performance-based strategies should be included in the implementation and monitoring step of the risk-informed decision-making process. The pilot programs may provide an opportunity for a more concrete definition and development of performance-based strategies."

B. PLANT-SPECIFIC APPLICATION OF SAFETY GOALS

The Safety Goal Policy Statement, issued by the Commission in 1986, established two qualitative safety goals to help assure that nuclear power plant operations do not significantly increase risk to individuals or to society. The policy statement also defined

two quantitative objectives for use "in determining achievement of the qualitative goals." These quantitative health objectives (QHOs) were defined in terms of a percentage (0.1%) of the total accidental and cancer death rates experienced by the public.

Since the policy statement was issued, the staff has developed subsidiary objectives to the QHOs. These subsidiary objectives have been formulated in terms of the frequency of core damage accidents and the performance of containment structures under accident conditions. These subsidiary objectives were established for a number of reasons, including that they introduced a clearer characterization of the desirable performance of some of the critical engineered barriers which protect public health (e.g., containment performance).

Consistent with the Commission's guidance in its June 15, 1990, SRM, the QHOs and subsidiary objectives have been pursued only in the context of generic regulatory decisions, such as generic backfit decision-making.

The Commission's PRA Policy Statement endorsed the expanded use of PRA in regulatory activities. This expansion, specifically in the area of changes to an individual plant's current licensing basis (CLB), has led the staff to consider the need for guidelines to support regulatory decision-making in plant-specific circumstances, recognizing that the use of risk information remains complementary to deterministic engineering analysis and judgment. Specifically, the staff is considering how to develop guidelines for plant-specific applications. The staff has identified two alternative approaches.

Alternative 1: Develop guidelines for plant-specific decisions that are derived from the Commission's current Safety Goals and/or subsidiary objectives.

This alternative involves the development of acceptance guidelines for risk-informed plant-specific CLB change requests, based on the current safety goals and/or subsidiary objectives. The staff and the nuclear power industry have experience in developing such acceptance guidelines. The NRC's Regulatory Analysis Guidelines, which are used in backfit determinations, include guidance on the acceptable levels of risk for a class of plants. In addition, EPRI's PSA Applications Guide contains proposed guidelines for judging the acceptability of plant-specific changes based upon their impact on plant risk.

The derived PRA-related acceptance guidelines would likely be in the form of core damage frequency and measures of containment performance, that are developed to be compatible with the Safety Goals and/or subsidiary objectives. The actual derivation could take different forms, for example:

- plant level guidelines related to plant design such as core damage frequency, conditional containment failure probability and early containment failure probability
- guidelines related to changes in risk such as change in CDF and that also limit cumulative increases from all changes
- guidelines that factor in actual site characteristics

PROS:

This alternative has the advantage of establishing acceptance guidelines which are closely related to criteria associated with the Safety Goals and/or subsidiary objectives. That is, plant-specific regulatory actions (i.e., changes to a plant's CLB) would be compared with acceptance guidelines that are derived from the Commission's Safety Goals to support plant-specific decisions.

The acceptance guidelines could be a combination of the above. The level of detail and scope of the risk information required would depend on the requested change and the acceptance guidelines. The technical content of the acceptance guidelines would be addressed as the Regulatory Guides and Standard Review Plans are developed. This alternative uses an integrated deterministic/probabilistic approach and would consider factors, such as defense-in-depth and compensatory measures, that may be difficult to quantify for impact on risk but that do provide qualitative or deterministic assurance that the risk impact is acceptable.

CONS:

The principal drawback of this approach is that it departs from previous Commission guidance on the use of safety goals. Plant-specific PRAs thus become a more prominent aspect of the decision-making process. Recognizing, however, that such increased prominence is a goal of the PRA Policy Statement, this drawback is not considered to be a fatal flaw in this alternative.

Explicit numerical guidelines could lead to litigation of regulatory decisions that use the guidelines. The use of numerical guidelines could increase the possibility of and difficulty inherent in litigation that would involve PRA. There are significant questions as to the ability of NRC to devote the resources needed to sustain PRA derived conclusions in the event there are numerous contested proceedings. In addition, to the extent that the safety goals or subsidiary objectives are relied upon for staff decisions, the goals or objectives would themselves be open to challenge.

Alternative 2: Relate plant-specific risk changes to industry population goals, i.e., calculate the risk at a plant after a proposed change and then assess this new plant risk against QHOs and subsidiary objectives (average) for the complete population of operating plants.

This alternative would maintain the generic nature of the Commission's Safety Goals while permitting their use in plant-specific regulatory actions. Plant-specific change requests would be compared with goals defined for the total population of plants.

PROS:

This alternative would maintain consistency with the underlying intent of the Commission's Safety Goals that the average risk of all operating plants be the numerical goal under consideration.

CONS:

A practical problem is that the impact of each plant-specific request would be compared with the distribution of plant risk estimates which would be essentially insensitive to all but quite large changes in risk in most plants. Therefore, many proposed changes could end up being acceptable from a risk perspective; thus in effect, making the deterministic factors the sole decision criteria. In addition, this alternative would not exclude trade-offs between large risk increases at some plants, and decreases at others. Complete risk estimates for all plants would likely be required, making this a very resource-intensive option.

STAFF RECOMMENDATION:

The staff recommends Alternative 1.

In its August 15, 1996 letter, the ACRS stated its belief that the safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications. The ACRS further stated that it is "impractical to rely exclusively on the Quantitative Health Objectives (QHOs) for routine use on an individual plant basis. Criteria based on core damage frequency (CDF) and large, early release frequency (LERF) focus more sharply on safety issues and can provide assurance that the QHOs are met. They should be used in developing detailed guidelines."

C. RISK NEUTRAL VS. INCREASES IN RISK

The resolution of this policy issue concerning whether to allow small increases in plant risk is closely linked with the previous policy issue associated with the development of guidelines for plant-specific risk-informed decisions.

Our current regulatory processes allow a qualitative consideration of risk or relative risk increases as part of our regulatory oversight. Accordingly, in certain instances, the Commission may approve license amendments or changes in a licensed facility when the probability or consequences of an accident may increase. Although plant modification under 10 CFR 50.59, cannot involve changes, tests, or experiments that increase the probability or consequences of an accident, the Commission has established a process for approving changes under 10 CFR 50.90 which reduce safety margin (i.e., increase risk). The approval process under 10 CFR 50.90 and 50.91 allows the staff to approve risk increases, but not significant risk increases without an opportunity for public hearing. Changes in Allowable Outage Times for equipment covered by Technical Specifications may be examples of this type of change.

The Commission, in its PRA Policy Statement, indicated that the use of risk insights should be increased and continue to complement and support the defense-in-depth philosophy. The staff will continue to use PRA techniques as an adjunct to the traditional engineering approach in order to better understand the risk significance of proposed CLB changes that impact the defense-in-depth attributes of plant design and operation. Guidance to support decision-making that integrates the results of both deterministic defense-in-depth

evaluations and risk evaluations is under development. This guidance will provide greater consistency in the staff review process and permit more structured consideration of the cumulative impact of risk increases.

Alternative 1: Allow small increases in risk under certain conditions, for proposed changes to a plant's licensing basis.

PROS

Current PRAs indicate that operating plants are generally below the NRC Safety Goal's quantitative health objectives. The QHOs already represent a small increase of the public risk (a factor of 1000 below existing accidental death or cancer risks). Additionally, subsidiary objectives for such parameters as core damage frequency and containment performance have been established to ensure the low likelihood of high consequence accidents. These subsidiary objectives have been shown to be even more restrictive than the overlying QHOs. For these reasons, increases that are a small portion of existing nuclear power plant risk are expected to produce a minimal change in public risk.

Additionally, some proposed changes may well represent small calculated risk impacts that are well within the bounds of uncertainties expected from the methods and available data. Therefore, very small calculated increases in plant risk may, in actuality, have no perceivable impact on public risk, even though in a calculational sense they are not precisely risk neutral.

As part of the development of risk-informed Regulatory Guides and Standard Review Plans, the staff is developing risk-informed acceptance guidelines based on subsidiary objectives such as CDF and large early release frequency and on the underlying risk profile of the plant. If this option is endorsed, the Regulatory Guides and SRPs will provide explicit guidance on what level of risk increase is acceptable. This approach will ensure the existence of more rigorous numerical guidelines for the NRC to utilize in an integrated decision process for assessing licensee initiatives.

CONS

A policy that allows the risk of plants to increase, even by an imperceptibly small amount, may be opposed by the public, regardless of whether there is a strong technical basis and it will result in other benefits (e.g., reduction in unnecessary burden). In addition, subsidiary objectives may become de-facto requirements.

Alternative 2: Require risk neutrality or risk reduction for proposed changes to a plant's licensing basis.

PROS

This approach would require that proposed changes to a plant's licensing basis either be risk-neutral (i.e., the increase in risk associated with a proposed change be compensated for by a compensatory action that will result in an equivalent decrease in plant risk) or result in a reduction in plant risk.

This type of approach would help assure that the plant risk will remain approximately constant or improve for those areas where staff approval is required.

CONS

The staff believes that this alternative is not compatible with the intent of the PRA Policy Statement objective of removing unnecessary conservatism from the regulatory process. Such an approach might also tend to restrict risk-informed applications where quantification limitations make it difficult or impossible to demonstrate with assurance that risk neutrality exists, even though the impact is insignificantly small.

Another disadvantage of this alternative is that it does not consider the actual observed variation in plant risk. Therefore, a licensee that manages risk and strives to keep plant risk low (e.g., a plant whose risk is 1 to 2 orders of magnitude better than some other plant) would be treated the same as licensees whose plants' risk profiles indicate a greater plant risk.

STAFF RECOMMENDATION

The staff recommends Alternative 1, which would permit increases in risk in some circumstances. The staff believes that this position is consistent with the Commission's Safety Goals. Increases in risk would only be considered when the staff determines that the proposed change will not result in an undue risk to the public, and that adequate protection to public health and safety will still be assured.

Additionally, the staff believes that the PRA Policy Statement was not intended to allow only risk-neutral changes. In its August 15, 1996, letter, the ACRS agreed with the staff that increases in risk should be permitted in some situations.

D. IMPLEMENTATION OF CHANGES TO RISK-INFORMED IST AND ISI REQUIREMENTS

Since 1992, the NRC has been working with the Nuclear Energy Institute (NEI) and other industry entities (e.g., ASME Research and industry owners groups) to develop guidelines for using probabilistic techniques to help better define inservice inspection (ISI) and inservice testing (IST) requirements. In late 1994, the staff began to encourage pilot applications of risk-informed methods to improve ISI and IST programs for nuclear systems and components. In late November 1995, the staff received requests from the Comanche Peak Steam Electric Station Units 1 and 2 and Palo Verde Nuclear Generating Station Units 1, 2, and 3 licensees to implement risk-informed IST programs in lieu of the ASME code-based IST program required by 10 CFR 50.55a.

Staff interaction with the industry and pilot licensees is continuing. The staff plans to proceed promptly on rulemaking, once the final Regulatory Guides and Standard Review Plans are in place. The staff's rulemaking effort will consider the appropriate guidelines and Code changes if the industry's consensus-based standards are available.
The staff identified three alternatives for implementing risk-informed inservice inspection and testing programs until rulemaking can be completed.

Alternative 1: Approve risk-informed ISI and risk-informed IST as exemptions to the current regulations

PROS

This alternative would (1) focus staff and industry resources on the more safety-significant components as well as provide early relief to the pilot plant licensees (i.e., cost savings and dose reductions) and (2) allow the staff to gain experience with risk-informed programs as risk-informed ISI and IST Regulatory Guides and Standard Review Plan sections are being developed and before rulemaking to modify 10 CFR 50.55a is initiated. This alternative would also provide the staff and industry with the flexibility they need to progress on risk-informed initiatives as staff review resources permit.

CONS

First, it would require more staff and licensee effort than Alternative 2 to address special circumstances as part of approving changes to pilot licensee IST and ISI programs. That is, the Commission would need to make a finding pursuant to 10 CFR 50.12, that "special circumstances" exist (i.e., that the proposed action would result in benefit to the public health and safety that compensates for any decrease in safety). This finding could be made if, for example, pilot plant licensees identified any non-Code components that should be categorized as high-safety-significant and focused on more testing for the high-safety-significant components while relaxing the inspection and test requirements for a selection of the low-safety-significant components.

Second, the NRC staff and industry will need to evaluate and possibly implement revised ISI/IST strategies, currently being developed by the industry (EPRI and owner's groups) and ASME, after initial approval of the risk-informed ISI/IST programs at the pilot plant sites. The staff has traditionally worked with ASME and the Code consensus process to define inservice inspection and testing requirements. Thus, implementing this option may bypass the traditional code consensus process and result in larger differences between licensee programs. If the staff proceeds with this alternative, pilot licensees with approved or exempted programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans.

Finally, under this alternative, the procedural aspects of granting exemptions (e.g., public notice) could require a substantial amount of staff resources. This alternative may be the least efficient alternative for the staff. The staff and the applicants would have more administrative burden for exemptions than with the other alternatives.

Alternative 2: Approve risk-informed ISI and IST changes approved as authorized alternatives under 10 CFR 50.55a (a)(3)(i)

The Director of NRR may authorize changes to licensee ISI and IST programs under 10 CFR 50.55a (a)(3)(i), and these changes would not be considered exemptions to the rule. Consequently, the Commission would not be required to make a finding pursuant to 10 CFR 50.12 that "special circumstances" exist. The staff is developing uniform criteria to further specify what constitutes "an acceptable level of quality and safety." These criteria could then be used to evaluate risk-informed ISI/IST program changes proposed by licensees.

Alternatives to the Code requirements have been authorized in the past when the proposed alternative provided an acceptable level of quality and safety or when compliance with the specified requirements would have resulted in a hardship or unusual difficulty without a compensating increase in the level of quality and safety. The staff has approved licensee requests made pursuant to 10 CFR 50.55a(a)(3) to accommodate situations such as the inability to conduct a quarterly component test without a plant shutdown.

PROS

Like Alternative 1, this alternative would (1) focus staff and industry resources on the more safety-significant components as well as provide early relief to the pilot plant licensees (i.e., cost savings and dose reductions) and (2) allow the staff to gain experience with risk-informed programs as risk-informed ISI and IST regulatory guides and standard review plan sections are being developed and before rulemaking to modify 10 CFR 50.55a is initiated. This alternative would also provide the staff and industry with the flexibility to continue making progress on risk-informed initiatives as staff review resources permit.

CONS

First, the staff would need to complete the development of the uniform criteria to specify "an acceptable level of quality and safety" using its own resources rather than utilizing industry-developed codes and standards.

Second, the staff has traditionally worked with ASME and the Code consensus process to define inservice inspection and testing requirements. Implementing this alternative for pilot licensees may be viewed as bypassing the ASME Code consensus process.

Finally, pilot licensees with approved programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans. If modifications were necessary, it would create an additional burden for pilot licensees.

Alternative 3: Defer approval of pilot plant risk informed ISI and IST programs until 10 CFR 50.55a has been modified

PROS

This alternative would allow the staff to complete the risk-informed ISI and IST Regulatory Guides and the Standard Review Plan sections before issuing safety evaluations for the pilot plant risk-informed ISI and IST programs. This alternative would also allow greater consideration of revised ISI and IST strategies, currently being developed by the industry and ASME.

CONS

First, this option would delay focusing NRC staff and industry resources on the more-safety significant components and delay potential cost savings and radiation exposure reductions associated with reducing ISI and IST requirements for low-safety-significant components. Second, a delay in considering risk-informed approaches, without a technical basis, or justifiable resource limitation, could be perceived as inconsistent with the Commission's own Policy Statement.

If the Commission chooses this alternative and directs the staff to withdraw, defer, or limit its participation in the risk-informed ISI and IST pilot programs, the risk-informed ISI and IST Regulatory Guides and Standard Review Plan sections, as well as proposed modifications to 10 CFR 50.55a, may not have the benefit of lessons learned from the development and implementation of pilot plant risk-informed ISI and IST programs.

STAFF RECOMMENDATION

The staff recommends Alternative 2, allowing the staff to further use the acceptable-alternative provision of 10 CFR 50.55a (a)(3)(i) to approve the pilot plants' applications. This alternative would provide the staff and industry the flexibility they need to progress on risk-informed initiatives as staff review resources permit.

The staff will continue to interact with ASME, industry owners groups, and licensees as the risk-informed ISI and IST programs evolve. It should be noted that, if the staff proceeds with this alternative, pilot licensees with approved programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans.

The staff plans to proceed promptly on rulemaking, once the final Regulatory Guides and Standard Review Plans are in place. If the development of industry guidelines and consensus-based standards keep pace, the staff's rulemaking effort will consider the appropriate guidelines and Code changes.

II. IMPLEMENTATION AND USE OF SUBSIDIARY SAFETY GOAL OBJECTIVES

As discussed in Section I, the staff recommends that acceptance guidelines for plant-specific CLB change requests be developed, based on the Commission Safety Goals and subsidiary objectives. The staff will continue to define such guidelines as part of developing SRPs and Regulatory Guides.

The staff is currently considering a decision-making logic that defines regions where the plant-specific guidelines can be used to characterize proposed changes in plant risk. This is conceptually similar to the Electric Power Research Institute's Probabilistic Safety Analysis Applications Guide. The staff is evaluating the appropriate number of regions, boundaries of the regions, and actions associated with those boundaries.

The development of the guidelines that can be applied on a plant-specific basis has resulted in the identification of a number of technical issues. These issues are included in Attachment 3 to the Commission paper and will be resolved during the development of the risk-informed Regulatory Guides and Standard Review Plans.

III. UNCERTAINTY IN THE IMPLEMENTATION OF RISK-INFORMED AND PERFORMANCE-BASED REGULATION

The implementation and use of subsidiary safety goal objectives in establishing acceptance guidelines for decision-making in risk-informed regulation is discussed above. The staff has identified technical issues that will be resolved as we move toward more risk-informed regulatory decision-making. The staff recognizes that this decision-making process must take account of the uncertainty associated with the PRA results.

Uncertainties arise from different sources. There are uncertainties in the values of the parameters of the PRA model (failure rates, initiating event frequencies, operator recovery rates, etc.), uncertainties related to the choice of models for elements of the PRA, and uncertainties due to the incompleteness of the PRA models. For example, in many PRAs, some modes of operation (low power and shutdown) and/or several initiating events (external events) are unanalyzed. The uncertainties of the first two types can be treated explicitly in PRAs to generate a characterization of the uncertainty on the PRA results, although it is not usual in Level I PRAs to include many modeling uncertainties, such as those associated with the choice of success criteria. Thus there are two classes of uncertainty associated with a PRA: those for which the impact is quantified, and those for which the impact is not quantified.

The staff intends, whenever possible, to use the mean value of the results of the PRA, evaluated from a formal uncertainty analysis, for comparison with the numerical guidelines associated with absolute risk measures such as core damage frequency. The guidelines, however, are not intended as "speed limits," so the comparison process has to allow some leeway to accommodate the analysis uncertainty. Thus the issue of the treatment of uncertainty is closely associated with how the subsidiary goal objectives will be used to set acceptance guidelines.

With respect to unanalyzed uncertainties such as those caused by incompleteness in the model, the staff is exploring several different approaches, such as establishing margins in the guidelines, compensating for the incompleteness by placing more emphasis on defense in depth, estimating the impact of the missing pieces in a conservative manner, or restricting the scope of the application.

These issues were discussed with the ACRS PRA Subcommittee on July 18 and August 7, 1996, and with the full ACRS on August 8, 1996. In its August 15, 1996, letter to Chairman Jackson, the ACRS noted that accounting for uncertainties is a difficult issue. The ACRS also noted that the staff's proposal to explore other options seems appropriate. The options include considering margins in acceptance criteria, placing more importance on defense-in-depth and others. Both the staff and the ACRS recognize that additional work remains to be done in this area.

ATTACHMENT 3

Summary of Key Technical and Process Issues

I) Issues Associated with Definition of Proposed change:

a) What information does the licensee need to submit to characterize the change?

b) Should the proposed change be required to meet at least one of the three goals of the PRA Policy Statement?

II) Issues Associated with Deterministic Evaluation:

a) What deterministic evaluations are required?

b) What are the acceptance guidelines for the deterministic evaluation?

III) Issues Associated with Risk Evaluation:

a) What determines the extent to which risk analysis can be used?

b) What determines the required quality of the risk analysis?

c) How is the appropriate quality assured?

d) How is uncertainty to be addressed?

e) How are cumulative changes in risk accounted for?

f) Should the acceptance guidelines be based upon total plant risk?

g) How should the acceptance guidelines be structured?

h) What is the role of importance analysis?

i) Should the acceptance guidelines apply to proposed changes individually or as a package?

IV) Issues Associated with Implementation and Monitoring:

a) What are the appropriate performance characteristics to monitor?

b) How should the SSCs to be monitored be selected?

c) How should the SSC performance be monitored?

d) How will feedback from the monitoring be used to make adjustments in implementation?

V) Issues Associated with Integrated Decision Making:

a) What are the important factors in integrating deterministic and probabilistic considerations?

b) How are uncertainties to be treated?

c) To what extent should the existing degree of defense-in-depth be maintained?

d) To what extent should the existing margins of safety be maintained?

e) What should defense-in-depth be based on?

f) What is the role of an expert panel?

g) What is the role of 10CFR50.109?

VI) Issues Associated with Documentation and Submittal:

a) What documentation is to be submitted?

b) What level of detail of risk information should be submitted?

c) Will explicit use of risk information in plant specific regulatory decisions require the licensee's PRA to be put on the docket and subject to litigation?