POLICY ISSUE
(Information)

April 23, 2004 SECY-04-0068

FOR: The Commissioners

FROM: William D. Travers
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SUBJECT: UPDATE OF THE RISK-INFORMED REGULATION IMPLEMENTATION PLAN

PURPOSE:

To present the Commission with the latest update of the Risk-Informed Regulation Implementation Plan (RIRIP), in accordance with a staff requirements memorandum (SRM) dated January 4, 2001.

BACKGROUND:

In a January 2000 memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. The strategy evolved into the initial version of the Risk-Informed Regulation Implementation Plan (RIRIP), which the staff provided to the Commission in March 2000. The Commission reviewed the plan and, after a briefing by the staff in March, directed the staff in April 2000 to include in the next update of the implementation plan an internal communications plan, staff training requirements, and a discussion of internal and external factors that may impede risk-informed regulation. The first complete version of the implementation plan was issued in October 2000.

In an SRM dated January 4, 2001, the Commission requested the staff to provide a more detailed communication plan (one that better highlights the agency's goal of improving public confidence), to prioritize activities, to identify necessary resources and tools, to address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations, and to identify critical-path activities and those that have crosscutting dimensions.

In response to the SRM, the December 2001 update of the RIRIP, specifically Part 2, included expanded arena chapters that describe the staff's progress in prioritizing the various implementation activities and identifying the necessary tools, critical-path activities, and activities that have crosscutting dimensions. The arena chapters also describe arena-specific activities related to communication with both internal and external stakeholders. This update of the RIRIP includes updates to the activity descriptions.

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DISCUSSION:

The RIRIP discusses the agency's actions to risk-inform its regulatory activities and specifically describes each of the activities identified as supporting the goals and objectives of the agency's Strategic Plan and the Probabilistic Risk Analysis Policy Statement.

The RIRIP has two parts. Part 1 provides a general discussion of the document's relationship to the Probabilistic Risk Assessment (PRA) Policy Statement and the Strategic Plan. It also discusses factors to consider in the process of risk-informing an agency requirement or practice, and provides guidance for selecting candidate requirements, practices and processes. Part 2 describes the staff's ongoing risk-informed regulation activities in the Reactor Safety arena and the Materials and Waste Safety arenas.

The last RIRIP (October 2003) stated that the staff redirected FY 2004 resources from the coherence program in the Reactor Safety arena to address risk-informed rulemaking priorities identified in the staff requirements memorandum on COMSECY-03-0029, "FY 2005 Budget," dated August 29, 2003. This prioritization was supported by the industry during the August 2003 PRA steering committee meeting. After staff reevaluation, future activities in the coherence program area were discontinued due to their relatively lower priority and a lack of resources. The staff has continued, however, specific efforts, such as risk-informing 10 CFR 50.46 and 10 CFR 50.48, to move forward with risk-informed regulations to address regulatory structure convergence with our risk-informed processes.

Attachment 1 describes the agency's risk-informing accomplishments since the last update. Key risk-informing activities to be conducted at the agency over the next 6 months, along with a brief background of each, are described in the paragraphs below.

Reactor Safety Arena

1. 10 CFR 50.69 (Special Treatment Requirements): On September 30, 2002, the staff submitted a proposed rule package (SECY-02-0176) that included a draft regulatory guide (DG-1121). The draft regulatory guide provided staff comments on and clarifications of the industry-proposed implementation guidance contained in draft Revision C of Nuclear Energy Institute (NEI) 00-04 ("10 CFR 50.69 System, Structure, and Component (SSC) Categorization Guideline"). The Commission issued an SRM on March 28, 2003, directing the staff to publish the proposed 10 CFR 50.69 for public comment. The proposed 10 CFR 50.69 was subsequently published for a 75-day comment period on May 16, 2003, and later extended by 30 days. The staff received 26 sets of comments containing hundreds of individual comments. Additionally, in November 2003, the staff received draft Revision D of NEI 00-04. The staff is currently reviewing this latest draft of the industry guidance document with the objective of endorsing this guidance in a regulatory guide with appropriate exceptions. The final rule package is scheduled to be provided to the Commission by June 30, 2004.

2. Phased Approach to Achieving Appropriate PRA Quality and Completeness: The staff is in the process of developing an action plan, as directed by the SRM on COMNJD-03-0002, "Stabilizing the PRA Quality Expectations and Requirements," dated December 18, 2003, and plans to provide it to the Commission in July 2004.

3. Creating a risk-informed environment: Phase 2 of the program has been completed and a report documenting the findings has been prepared. The report clearly lays out the critical elements of a risk-informed environment and approaches for establishing those elements in the reactor program. Over the next year the staff will recommend additional changes in NRR activities to further incorporate these elements.

4. Option 3 (Risk-Informing Part 50)

   – In SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendation on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)," the staff recommended the development of risk-informed approaches to technical requirements in 10 CFR 50.46 (and related provisions) concerning LOCA acceptance criteria and evaluation models. In its March 31, 2003 SRM, the Commission directed the staff to undertake rulemakings, one of which would develop a proposed rule to allow, as a voluntary alternative, a redefinition of design basis maximum break size. The SRM included other directions on the Commission's expectations for the rule. It also asked the staff to keep the Commission informed of progress.

   – In SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of-Offsite Power" dated March 2004, the staff requested direction and additional guidance on policy issues that would facilitate resolution of identified technical issues. The technical issues include (1) the alternate break size selection matrix, (2) appropriate limitations on what modifications are allowed in a plant and how they change the risk profile, (3) defense-in-depth considerations, and (4) the appropriate level of mitigative capability which should remain for breaks beyond the new design basis.

   – In SECY-04-0060, "Loss-of-coolant Accident Break Frequencies for the Option III Risk-informed Reevaluation of 10 CFR 50.46, Apprndix K to 10 CFR Part 50, and General Design Criteria (GDC) 35," dated April 13, 2004, the staff informed the Commission of the update preliminary LOCA frequency estimates and the technical basis for these frequencies. Follow-on work to finalize these estimates is planned. The information provided by this effort will help the staff address the alternate design-basis LOCA break size component of the Part 50.46 rulemaking effort.

5. The staff worked with the National Fire Protection Association (NFPA) to develop an alternative performance-based and risk-informed fire protection standard for nuclear power plants. This standard, NFPA-805, was issued in April 2001. The staff published a proposed rule on November 1, 2002. The public comment period ended January 15, 2003. The comment resolution document was developed with the assistance of OGC and a *Federal Register* notice package was prepared for concurrence. The ACRS full committee was briefed on the final rule on December 4, 2003. The final rule package will be provided to the Commission by April 2004 and will be published upon

Commission approval. The staff is currently working with the industry to develop the implementation guidance for NFPA 805, which will be endorsed by the NRC in a regulatory guide.

6. Risk Management Technical Specifications (RMTS): The staff continues to work on the eight RMTS initiatives for risk-informing the standard technical specifications (STS) and making the STS more consistent with the Maintenance Rule (10 CFR 50.65(a)(4)).

   – Initiative 1, Modified End States: This initiative would permit, after a risk assessment, for some systems, entry into hot shutdown rather than cold shutdown to repair equipment. The Combustion Engineering Owner's Group (CEOG) and Boiling Water Reactor Owner's Group (BWROG) topical reports have been issued and the industry has proposed technical specifications changes which are under staff review. The CE STS change (TSTF-422) is expected to be made available through the Consolidated Line Item Improvement Process (CLIIP) by September 2004.

   – Initiative 4, Risk-Informed Completion Times: This initiative would permit, contingent upon the results of a plant configuration risk assessment, temporary extension of the existing completion time within an LCO using a quantitative implementation of 50.65(a)(4). The staff provided acceptance review comments to the Risk Management Guidance Document, the CE pilot proposal, TSTF-424, and the South Texas Project pilot proposal. The industry will update the RMTS Risk Management Guidance, CE TSTF-424, and the STP pilot proposals. The staff briefed the ACRS in March 2004.

   – Initiative 5, Relocation of Surveillance Frequencies: This initiative would permit Surveillance frequencies to be determined in and relocated to a licensee-controlled TS program. The industry is developing an Initiative 5b methodology. Limerick and Peach Bottom have volunteered to be pilot plants to test the proposed program and procedures. The industry will submit, in April 2004: the Limerick pilot license amendment request; a Methodology Document; and, the associated proposed technical specifications changes, TSTF-425.

   – Initiative 7, Non-TS support system impact in TS System Operability: This initiative would permit a risk-informed delay time prior to entering LCO actions for inoperability due to loss of support function provided by equipment outside of tech specs; TSTF-372 addresses snubber inoperability and TSTF-427 addresses hazard barrier inoperability. In response to staff feedback, the industry will submit a revision to TSTF-372, on snubber inoperability, and draft implementation guidance to TSTF-427, on barriers, in April 2004.

7. The staff issued Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," for trial use in February 2004. RG 1.200 provides guidance to licensees for determining the technical adequacy of a PRA used in risk-informed integrated decisionmaking processes and with respect to endorsing industry guidance.

Appendix A of RG 1.200, updated February 27, 2004, addresses the American Society of Mechanical Engineers' (ASME) Addenda A. Addenda A of the ASME standard addressed and resolved the majority of the staff's objections noted in the draft guide. The remaining staff objections, as noted in the RG, will be addressed and their resolutions tested during the trial use period. RG 1.200 will be tested via several pilot plants:

- Columbia - DG AOT extension
- San Onofre - battery AOT extension
- Surry - 50.69 (charging and CCW systems)
- Limerick - TS 5b (surveillance test interval extension)
- South Texas - TS 4b (flexible AOTs)

8. The American Nuclear Society issued a PRA standard for external events, "American National Standard External Events PRA Methodology," ANSI/ANS-58.21-2003, in December 2003. The staff has initiated its review and will provide its comments in Appendix C of RG 1.200. The staff expects to issue a draft of the appendix for public review and comment by August 2004.

9. The staff has recently issued NUREG-1784, "Operating Experience Assessment - Effects of Grid Events on Nuclear Power Plant Performance." This report was completed before the August 14, 2003 northeast U.S. electric power blackout event. Following the August event, the staff has followed up with an assessment of the near-term implications of potential issues concerning the nation's electrical power grid. The specific objective of the study included the identification of safety-significant tendencies that could be attributed to a perceived decline in grid reliability as an indirect result of deregulation. The staff has completed preliminary accident sequence precursor analyses for the eight plants that lost offsite power during the August 2003 event. The staff has also started the analysis of an updated station-blackout risk using updated loss of offsite power frequencies and recovery probabilities. The results from these analyses will provide the technical basis for assessing the need for changes to the current regulations concerning grid reliability. A draft report will be available for public review in January 2005.

10. In December 2002, RES forwarded to NRR a draft NUREG report, "Technical Basis for Revision of the Pressurized Thermal Shock (PTS) Screening Criteria in the PTS Rule (10 CFR 50.61)." This report documents the results of a multiyear study reevaluating the technical basis of 10 CFR 50.61. The draft report is currently being peer-reviewed, and will be modified to reflect the comments. The results will be published as a final NUREG report in September 2004. The draft results from this project confirm that the calculations which provide the basis for the current PTS rule (10 CFR 50.61) contain significant unnecessary conservatisms. If approved in rulemaking, these new results suggest that PTS would not limit the safe operational life of any currently operating PWR even for operational durations now being considered for license extension.

11. The staff is revising NUREG/CR-6595, “An Approach for Estimating Frequencies of Various Containment Failure Modes and Bypass Events,” which describes an approach for estimating large early release frequency (LERF). RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-informed Decisions on Plant Specific Changes to the Licensing Basis” Revision 1, dated November 2002, references this report as providing a simple screening method for assessing LERF. NUREG/CR-6595 currently includes some considerations for low-power and shutdown (LPSD) operation, but does not include a simplified Level 2 analysis focusing specifically on LPSD. The objective of the revision is to include a simplified Level 2 probabilistic risk analysis specifically for LPSD conditions, similar to the PRA for full-power operations. This analysis should be adequate to produce an estimate of LPSD risk in terms of radionuclide release frequency when coupled to a Level 1 analysis. The staff will perform a literature search to identify containment failure modes and mechanisms unique to shutdown, develop LPSD Level 2 simplified event trees and guidance, test and modify the trees and guidance, and coordinate the effort on the LPSD PSA standard with the American Nuclear Society. The full-power LERF modeling approaches used in the report will also be updated. The staff is reviewing public comments received on the draft revision and then will finalize the report. The report is expected to be completed by August 2004.

12. The staff is developing an improved PRA model to allow determination of the frequency of containment bypass events due to steam generator (SG) tube failures in PWRs, utilizing materials and thermal-hydraulic analyses that have been underway for several years. The improved PRA model will calculate the likelihood of SG containment bypass events (i.e., SG tube failures that would be likely to occur before failure of other components that would result in primary coolant discharge inside containment only). This improved PRA model is to be completed in April 2004. The improved PRA model will be used to calculate the frequency of SG containment bypass events at an example plant in August 2004. Initially, the staff will determine the frequency of tube and other material failures resulting from postulated severe accidents. Later, the staff will also consider steam generator tube ruptures resulting from non-severe-accident initiators (e.g., main steamline breaks). The improved model will allow a more realistic determination of the frequency of containment bypass events due to severe accident-induced steam generator tube failures. These determinations are intended to confirm that existing requirements and guidance effectively limit the risk due to containment bypass events.

13. The staff, in coordination with EPRI, is developing risk-informed methods to estimate fire risk. These methods will be based on demonstration studies that will develop insights and guidance for fire risk analysis (FRA). The staff expects to complete development of methods from the two PWR pilot plants by October 2004. A licensee with a BWR plant has agreed to participate in these studies, and RES and EPRI staff expect to begin work in May 2004.

14. To support licensing activities and evaluate the risk associated with the review of advanced reactor designs, sufficient knowledge must be acquired to allow adequate review of the proposed passive systems. As part of this work, the staff is reviewing existing information on passive systems and the modeling of passive systems. The staff will issue a report discussing the passive system modeling survey results in May 2004.

Waste Safety and Materials Safety Arenas

1. In support of the Commission's policies on risk-informing the regulatory process and performance goals, the staff is working to develop probabilistic risk assessment methods and quantify the risk of dry storage of spent nuclear fuel. These studies (Phases I and II) are intended to accomplish the following objectives: (a) provide methods to quantify the risk of dry cask storage of spent nuclear fuel, (b) provide insights into decisionmaking and improving 10 CFR Part 72 regulatory activities, and (c) provide analytical tools that can be used to implement future waste safety goals and risk-informed regulatory activities.

   – Phase I: In February 2003, RES completed a draft pilot PRA on dry cask storage with a specific cask design. RES is currently revising the draft report to incorporate peer review comments. The staff plans to discuss this study with the joint ACRS/ACNW subcommittee in September 2004, and publish the final pilot PRA in 2005.

   – Phase II: Additional studies have been identified to broaden the application of the pilot PRA method. The pilot PRA method and additional studies will enable SFPO to (1) develop a framework for evaluating potential PRAs performed by industry to support specific licensing actions; and (2) develop generic insights that can be used with other parallel, risk-informing efforts in SFPO. RES and SFPO expects to complete the additional studies in FY2005 and FY2006. An expected outcome is an enhanced regulatory focus on dry cask safety issues, that is more commensurate with the associated risk importance of such issues. This will maintain safety, enhance efficiency and effectiveness in SFPO, and potentially reduce unnecessary regulatory burden in the dry cask storage industry.

2. During NMSS's Phase I work to ascertain the feasibility of implementing safety goals (later designated as risk guidelines) completed in FY 2001, the Risk Task Group (RTG) concluded that quantitative risk guidelines could be useful in risk-informing certain applications in the Materials and Waste areas. Consequently, the staff is working to develop applicable risk guidelines and a risk-informed decisionmaking process for NMSS. The utility of this decision process and the associated risk guidelines is being tested and revised as needed through a series of pilot studies. The staff will revise the draft risk-informing guidance for NMSS based on the insights gained from the pilot studies. The staff is also in the process of integrating the various draft NMSS risk-informing guidance documents and plans to complete the integration by June 2004.

3. The staff plans to complete implementation plans for the recommendations in both the license termination rule (LTR) analysis (SECY-03-0069) that the Commission approved and the recommendations in the Decommissioning Program Evaluation. The staff is integrating these plans and will combine them into a single plan that will contain specific staff activities and schedules to complete the approved recommendations, some of which will further risk-inform the Decommissioning Program. For the LTR analysis these include (1) applying a risk-informed graded approach for using institutional controls to restrict the future use of a site, (2) expanding the use of more realistic exposure

scenarios using a risk- informed approach, and (3) risk-ranking operating sites and activities to focus NRC inspections and licensee monitoring and reporting and avoid creating future "legacy" sites that would have difficult and costly decommissioning problems. For the Decommissioning Program Evaluation these include (1) implementing the Consolidated Decommissioning Guidance and explaining the risk-informed approach to staff and licensees by developing examples, case histories, and lessons learned, and (2) defining and managing all decommissioning sites using a graded approach to prioritize, allocate, and track both licensing and inspection resources based on site-specific risk insights and decommissioning challenges.

4. The HLW program staff will continue to use risk information and insights to risk-inform its many pre-licensing activities and prepare for the review of a DOE license application for a repository at Yucca Mountain. The staff will continue to risk-inform its review of DOE's issue resolution agreement submittals by using the risk insights baseline document as a reference to understand the risk significance of the technical issues addressed by the agreements and to focus its review on the more risk-significant aspects of the submittals.

5. The staff will continue to develop a risk-informed Yucca Mountain inspection program. The inspection program will rely on risk information to ensure that inspection resources are being appropriately applied. The staff is developing guidance to (1) focus inspections based on risk significance, (2) enhance current enforcement policy to reflect a risk-informed view on potential violations and redirect resources as necessary, and (3) develop a Yucca Mountain oversight process to trend DOE performance.

6. The staff will continue to refine the risk insights baseline for the potential Yucca Mountain repository as new risk information becomes available. The staff is currently conducting a series of focused risk analyses. The risk analyses will allow the staff to strengthen the quantitative information supporting the risk insights and to reduce uncertainties associated with the risk insights. The staff plans to update the risk insights baseline before receiving a license application from DOE. The staff briefed the Advisory Committee on Nuclear Waste on the status of the risk insights initiative in February 2004.

7. RES has initiated a feasibility/scoping study to identify and develop simple methods of incorporating human factors and estimating human reliability for the wide range of situations encountered and activities performed by NMSS licensees. The draft report was completed by RES in December 2003 and is under peer review. On the basis of this study, RES and NMSS will jointly determine the need and prioritize the development of simple human reliability assessment (HRA) methods and tools for both the materials and the waste applications.

RIRIP Content and Organization:

The RIRIP (Attachment 2) is divided into two parts. Part 1 describes the plan's relationship to the PRA Policy Statement and its relevance to the NRC's Strategic Plan. Part 1 also discusses certain key features of the traditional deterministic approach that should be preserved in establishing risk-informed regulatory programs, since risk information will be used to complement the traditional approach. In addition, Part 1 provides draft guidance that the staff has used for selecting candidate requirements, practices, and processes to risk-inform.

Part 2 describes the staff's risk-informed regulation activities, with chapters addressing the Reactor Safety arena and the Materials and Waste Safety arenas. Each chapter is organized around the Strategic Plan strategies that are relevant to risk-informed regulation in the given arena. In addition, each chapter describes the implementation activities for each strategy and identifies significant milestones and training and communications considerations for each activity. Relationships among implementation activities are described and critical-path items are identified. Gantt charts for some of the implementation activities are also provided to illustrate the relationships among tasks within activities.

The staff recognizes that a revised strategic plan has been developed, as well as a new budget structure for FY 2005 budget execution. Upon Commission approval of the revised plan, the RIRIP will be realigned to coincide with the new strategic objective and general goals.

RESOURCES:

In response to the Commission's direction regarding the October 2000 version of the RIRIP, the plan lists the priority rating of each risk-informed regulation implementation activity. These priorities were determined through the Planning, Budgeting, and Performance Management (PBPM) process. As part of the FY 2005 PBPM process, the program offices developed a common prioritization methodology and used it to produce a prioritized listing of planned activities by arena (reactor, materials, and waste) for the offices. This prioritized listing will continue to be used to inform both arena-level resource budgets and reprogramming, as necessary. As with other staff activities, changes to the resources allocated to implementation activities for risk-informed regulation will continue to be made consistent with the PBPM process to reflect changes to the agency's budget and priorities.

COORDINATION

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the General Counsel has also reviewed this paper and has no legal objections.

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Attachments: 1. Table of Accomplishments
2. Risk-Informed Regulation Implementation Plan

Part 2 describes the staff's risk-informed regulation activities, with chapters addressing the Reactor Safety arena and the Materials and Waste Safety arenas. Each chapter is organized around the Strategic Plan strategies that are relevant to risk-informed regulation in the given arena. In addition, each chapter describes the implementation activities for each strategy and identifies significant milestones and training and communications considerations for each activity. Relationships among implementation activities are described and critical-path items are identified. Gantt charts for some of the implementation activities are also provided to illustrate the relationships among tasks within activities.

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