

## **POLICY ISSUE INFORMATION**

October 25, 2004

SECY-04-0197

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

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.

SUMMARY:

This paper provides a summary of the agency's significant risk-informing accomplishments since the previous version of the RIRIP (Attachment 1), as well as providing the latest update of the RIRIP (Attachment 2), which details activities designed to support the agency's Strategic Plan and the Probabilistic Risk Assessment (PRA) Policy Statement.

This paper also summarizes the significant risk-informing activities to be conducted over the next 6 months. These activities are in the areas of fire protection, risk-informing the acceptance criteria for emergency core cooling systems for light-water nuclear power reactors (10 CFR 50.46), the coherence program, PRA quality, the risk-informed (regulatory) environment, new reactor licensing, the reactor oversight process, dry cask storage, high-level waste, and risk-informed requirements for fuel cycle safety.

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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 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 asked the staff to provide a more detailed communication plan, 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 their 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 resources and tools, critical-path activities, and activities that have crosscutting dimensions. The arena chapters also described arena-specific activities related to communication with both internal and external stakeholders.

DISCUSSION:

Attachment 1 is a Table of Accomplishments which 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.

Attachment 2 is the RIRIP which discusses the agency's actions to risk-inform its regulatory activities and describes each of the activities identified as supporting the goals and strategies of the agency's Strategic Plan and the Probabilistic Risk Assessment (PRA) Policy Statement. It 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 for Fiscal Years (FY) 2000 - 2005. Part 1 also discusses 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 to select 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 currently organized around the strategies defined in the Strategic Plan for FY 2000 - 2005 as they relate to risk-informed regulation in the given arena. Each chapter describes the implementation activities for each strategy and identifies significant milestones, training, and communication-related 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.

In August 2004, the agency issued a revised Strategic Plan for FY 2004 - 2009. This new plan established five goals and the associated strategies that the agency will use to achieve each goal. Specifically, these five goals are safety, security, openness, effectiveness, and management. In response, the staff is in the process of restructuring the RIRIP to make future updates consistent with the five new goals in the agency's revised Strategic Plan. Toward that end, this RIRIP update also lists and prioritizes the primary and secondary performance goals and strategies identified in the Strategic Plan as they relate to each activity in the RIRIP. The specific priority associated with each activity was determined through the NRC's Planning, Budgeting and Performance (PBPM) process for FY 2006. This restructuring will continue as the staff refines the planned activities in the next RIRIP update to reflect any changes in the agency's priorities resulting from the issuance of the revised Strategic Plan.

### Reactor Safety Arena

1. Fire Protection (RS-MS8-6): The staff completed the rulemaking to endorse an alternative performance-based and risk-informed fire protection standard for nuclear power plants. The staff worked with the National Fire Protection Association (NFPA) to develop NFPA Standard 805, which was issued in April 2001. The final rule to incorporate NFPA 805 in Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50) was published in the *Federal Register* in June 2004. The staff is working with the industry to complete development of the implementation guidance for NFPA 805, which will be endorsed by the NRC in a regulatory guide.
2. Change Technical Requirements for 10 CFR 50.46 (RS-MS8-3): In response to an SRM dated July 1, 2004, regarding SECY-04-0037, the staff is currently working on a proposed rulemaking to risk-inform the requirements of 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors." The staff is scheduled to complete a proposed rule by December 2004. As part of this work, the staff also completed the preliminary frequency estimates for a loss-of-coolant accident (LOCA). The results of this effort were provided in SECY-04-0060 in April 2004. The staff expects to complete the work on revised LOCA break size frequency estimates by December 2004.
3. Coherence Program (RS-EER1-8): In response to an SRM dated February 8, 2002, , the staff developed a plan for improving coherence among risk-informed activities. The goals of this plan were to develop a program demonstrating that the reactor regulations and staff processes are built on a unified safety concept and are properly integrated so that they complement one another. Each part of the plan has taken advantage of and built on ongoing staff activities. The staff issued the plan for internal management review but, due to redirection of resources to address higher priorities, the plan was not implemented. However, the staff continued with specific efforts (e.g., 10 CFR 50.46 and 50.69) to address regulatory structure convergence with our risk-informed process. The staff currently plans to issue a revised coherence program plan for internal management review in December 2004.
4. PRA Quality (RS-EER1-9): The staff is working on the implementation of the action plan for the Phased Approach to Achieving Appropriate PRA Quality and Completeness, documented in SECY-04-0118. This work includes identifying the current risk-informed applications, specifying the PRA needs for these applications, developing a prioritization

process for staff review, and developing a Phase 2 schedule. The staff expects to complete these tasks by December 2004.

5. Develop standards with National Standards Committees (RS-EER1-2): In December 2003, the American Nuclear Society (ANS) issued the "American National Standard External Events PRA Methodology," ANSI/ANS-58.21-2003. The staff reviewed the standard and developed a preliminary position, which will be documented in Appendix C to Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." A preliminary draft of Appendix C to RG 1.200 was issued in August 2004 to solicit early feedback from stakeholders on the staff's initial assessment of the ANS standard. Revision 1 to RG 1.200, which will include Appendix C, is scheduled for public review and comment in midyear 2005.
6. Assess Adequacy of PRA Results (RS-EER1-7): The staff issued 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. The American Society of Mechanical Engineers (ASME) is updating the "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (ASME RA-S-2002) and plans to issue Revision 1 in early 2005. The Nuclear Energy Institute (NEI) plans to update and issue its self-assessment process (NEI-00-02) based on Revision 1 to the ASME standard shortly thereafter. The staff plans to update RG 1.200 to reflect the lessons learned from the industry pilots during the trial period, Revision 1 of the ASME standard, and Revision 1 to NEI-00-02 (all which are expected to be completed by April 2005). Pilot studies at the Columbia Generating Station and Limerick are in progress. The three remaining pilot studies at Surry, San Onofre, and South Texas Project (STP) are expected to be completed by December 2004.
7. Assess Adequacy of PRA Results (RS-EER1-7): The PRA standards, RG 1.174 and RG 1.200, allow the analyst to use supplementary approaches to account for scope items or technical requirements that are not addressed in its PRA. In risk-informed decision-making, an understanding of the key uncertainties is a fundamental piece of the process. The staff has initiated efforts to develop guidance on the following topics:
  - C Acceptable approaches to supplement a PRA that is not of a full scope, or has deficiencies in some elements which includes the appropriate use of bounding analyses, screening methods, or qualitative approaches
  - C Identification and performance of sensitivity studies
  - C How to use the results from the uncertainty analyses in the decision-making process, including the role and definition of defense-in-depth

A draft guidance is expected to be completed for staff review by December 2004.
8. Methods for Calculating Risk (RS-EER1-3): The staff is preparing Draft Regulatory Guide (DG) 1136, "Guidance for Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire," which will accompany the revision of Section III.G.2 of Appendix R to 10 CFR Part 50. DG 1136 will provide detailed guidance on how to implement the feasibility and reliability criteria developed by the staff

for the post-fire manual actions as part of the revision of Appendix R Section III.G.2. DG 1136 will be sent to the Commission in December 2004 with the proposed rule.

9. Creating a Risk-Informed Environment (RS-EER1-1): A report documenting the findings from Phase 2 has been completed. The report clearly lays out the critical elements of a risk-informed environment and approaches for establishing those elements in the reactor program. A plan has been developed for implementing changes in the reactor program to enhance the current environment for risk-informed regulation. The plan was presented to the leadership team in the NRC's Office of Nuclear Reactor Regulation (NRR) in July 2004. The NRR leadership team is currently considering which of the initiatives proposed in the plan to pursue in FY 2005.
10. New Plant Licensing (RS-MS8-10): In SECY-03-0059, "NRC Advanced Reactor Research Program," dated April 18, 2003 (ADAMS Accession #ML023310534), the staff discussed its plan for developing a technology-neutral framework for new plant licensing. In SECY-04-0103, "Status of Response to the June 26, 2003, Staff Requirements Memorandum on Policy Issues Related to Licensing Non-Light-Water Reactor Designs," dated June 23, 2004 (ADAMS Accession #ML041140521), the staff indicated that a draft framework would be issued for public review and comment and would be provided to the Commission in December 2004. This framework will provide guidance and criteria for the staff to use in developing technology-neutral requirements. The staff has had continual interactions with both internal and external stakeholders, including Advanced Reactor Steering Committee briefings, briefings of agency management in NRR, the NRC's Offices of Nuclear Regulatory Research (RES) and the General Counsel (OGC), the Advisory Committee on Reactor Safeguards (ACRS), and public meetings.
11. Assessing Fire Safety (RS-EER1-4): The staff, in coordination with the Electric Power Research Institute (EPRI), is developing risk-informed methods to estimate fire risk. This will include demonstration studies that will develop insights and guidance for fire risk analysis (FRA). The staff expects to complete a report on the development of methods from the two pressurized-water reactor (PWR) pilot plants by April 2005. A licensee with a boiling-water reactor (BWR) plant has agreed to participate in these studies, and NRC and EPRI staff began work in May 2004.
12. Risk Management Technical Specifications (RMTS) (RS-MS8-5): The staff continues to work on the eight RMTS initiatives to risk-inform the standard technical specifications (STS) and make them more consistent with the Maintenance Rule [10 CFR 50.65(a)(4)]. The major activities in this area are summarized below:
  - C Initiative 1, Modified End States: This initiative would allow (after a risk assessment) some systems to enter hot shutdown rather than cold shutdown to repair equipment. The safety evaluation reports (SER) have been issued for the Combustion Engineering Owners Group (CEOG) and Boiling-Water Reactor Owners Group (BWROG) topical reports, and the industry has proposed technical specification changes which are under staff review. The staff provided comments on the draft implementation guidance for the Combustion Engineering (CE) STS change, TSTF-422, in July 2004, and the issues are currently being

resolved. TSTF-422 is expected to be available through the Consolidated Line Item Improvement Process (CLIIP) in December 2004.

- C Initiative 4, Risk-Informed Completion Times: Contingent on the results of a plant configuration risk assessment, this initiative would permit a temporary extension of the existing completion time within a limiting condition for operation (LCO) using a quantitative implementation of 10 CFR 50.65(a)(4). The staff provided requests for additional information (RAIs) concerning the Risk Management Guidance Document, the CE pilot proposal, TSTF-424, and the STP pilot proposal. The industry will respond to the RAIs and update the RMTS Risk Management Guidance, CE TSTF-424, and the STP pilot proposals by December 2004.
  - C Initiative 5, Relocation of Surveillance Frequencies: This initiative would permit surveillance frequencies to be determined in and relocated to a licensee-controlled technical specification (TS) program. Limerick has submitted the pilot plant license amendment request. The industry is developing an Initiative 5b methodology, and will submit a methodology document and the associated proposed technical specification changes, TSTF-425, in December 2004.
  - C Initiative 6, Modification of LCO 3.0.3, Actions and Completion Times: For specific systems, this initiative would convert default or explicit entry into the LCO 3.0.3 shutdown track to a predetermined completion time for corrective action, prior to beginning shutdown. The staff approved and issued the SER on the CE topical report on July 9, 2004. The industry will submit a proposed CE TSTF-426 in the near future, and staff approval is scheduled for December 2004.
  - C 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. The staff approved and issued the safety evaluation for TSTF-372 in September 2004 and is scheduled to make TSTF-372 available via the CLIIP in December 2004. The safety evaluation for TSTF-427 is scheduled to be issued in October 2005, with availability via CLIIP in December 2005.
13. Pressurized Thermal Shock Rule Revision (RS-MS8-7): In December 2002, RES forwarded to NRR a draft staff 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 report in December 2004. The draft results from this project confirm that the calculations which provide the basis for the current PTS rule contain significant unnecessary conservatisms. These new results suggest that PTS will not limit the safe operational life of any currently operating PWR even for operational durations now being considered for license extension.

14. Assessing Steam Generator Performance (RS-MS8-9): The staff is developing an improved PRA model for use in determining the frequency of containment bypass events that result from steam generator (SG) tube failures induced by severe accident conditions. This work utilizes materials and thermal-hydraulic analyses that have been underway for several years. The improved PRA model will be used in a trial application to calculate the frequency of SG containment bypass events at a pilot plant in December 2004, and will be improved based on lessons learned during that application. The results from further applications of the improved model will be used to evaluate the acceptability of existing requirements and guidance in effectively limiting the risk associated with containment bypass events.
15. Methods for Calculating Risk (RS-EER1-3): The weakness of available data for human reliability analysis (HRA) is one of the biggest concerns expressed by practitioners and decision-makers. Furthermore, NRC activities supported by human factors (HF) research are constrained by the lack of a database that analysts could draw on when addressing various regulatory issues. To address this need, the staff is developing a Human Event Repository and Analysis (HERA) database. Previous efforts had focused on developing a structure for collecting human performance information in a format suitable to HRA and HF applications regardless of the specific tool or method that an analyst uses. Currently, the staff is populating the HERA database with human events found in licensee event reports and is developing quantification processes allowing the use of these data to estimate human failure event probabilities. The HERA data collection and coding activity is closely coordinated with the component database called "Integrated Data Collection and Coding System." A draft report on the development and use of HERA will be completed for NRC peer review by December 2004.
16. Methods for Calculating Risk (RS-EER1-3): In July 2004, the staff issued draft NUREG-1792, "Good Practices for Implementing Human Reliability Analysis (HRA), Draft Report for Comment." The HRA good practices were developed as part of the NRC activities for addressing PRA quality issues and provide guidance for implementing RG 1.200. NUREG-1792 provides a technical basis for performing an HRA or for formulating questions to evaluate the quality of HRA. NUREG-1792 will be revised to address public comments and will be published by April 2005.
17. Reactor Oversight Process (RS-MS3-1): During FY 2004, the staff developed the Mitigating Systems Performance Index (MSPI) in support of the reactor oversight program and piloted it in 20 plants. MSPI will monitor risk associated with changes in performance of selected mitigating systems, accounting for plant-specific design and performance data. The MSPI addresses known problems with the existing safety system unavailability performance indicator and provides a measure of both system reliability and availability. The pilot program exercised the MSPI guidance, did validation and verification, and performed temporary instruction inspections. The final staff report documenting development of the MSPI, including results from the pilot program, is expected to be published in early 2005.

Waste Safety and Materials Safety Arenas

1. PRA of Dry Cask Storage (WS-MS1-1): 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 provide: (a) methods to quantify the risk of dry cask storage of spent nuclear fuel, (b) insights into decision-making and how to improve 10 CFR Part 72 regulatory activities, and (c) analytical tools that can be used to implement future waste safety goals and risk-informed regulatory activities.
  - C Phase I: In February 2003, RES completed a draft pilot PRA of 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/Advisory Committee on Nuclear Waste (ACNW) subcommittee in April 2005 and will publish the final pilot PRA in 2006.
  - C Phase II: Additional studies will be identified in November 2004 to broaden the application of the pilot PRA method. The pilot PRA method and additional studies will enable the NRC's Office of Nuclear Materials Safety and Safeguards (NMSS) Spent Fuel Project Office (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 expect to complete the additional studies in FY 2005 and FY 2006. An expected outcome is an enhanced regulatory focus on risk-important dry cask safety issues. This will maintain safety, enhance efficiency and effectiveness in SFPO, and potentially reduce unnecessary regulatory burden in the dry cask storage industry.
2. Develop Framework for Risk-Informing the NMSS Regulatory Process (MS-EER1-1): The staff has developed a risk-informed framework for regulating the materials and waste arena. The staff plans to transition from developmental work to trial application of the proposed systematic risk-informing decision-making approach on routine materials and waste activities. Beginning in October 2004, staff will start selecting activities to explore during trial applications on how a risk-informed approach could be used to make a decision in licensing casework, inspection activities, rulemaking, and guidance development.
3. Risk-Inform High-Level Waste (HLW) Framework (WS-MS1-3): 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 license application that the U.S. Department of Energy (DOE) plans to submit 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 Report, forwarded to the Commission on April 29, 2004, as a reference to understand the risk significance of the technical issues addressed by the agreements and to focus the staff's review on the more risk-significant aspects of the submittals.

4. Risk-Inform High-Level Waste (HLW) Framework (WS-MS1-3): To support a risk-informed license application review, the staff will continue to refine the Risk Insights Baseline for the potential Yucca Mountain repository as new risk information becomes available. Currently, the staff is completing a series of focused risk analyses to strengthen the quantitative information supporting the risk insights and to better understand uncertainties in the risk insights. The staff plans to review its Risk Insights Baseline in light of the new risk information before receiving a license application from DOE.
5. Revise Part 70 (MS-MS2-3): The staff will continue reviewing the implementation of the upgrade to 10 CFR Part 70 Subpart H. The staff will ensure that licensees are meeting the Commission's objectives for a risk-informed and performance-based regulatory approach for fuel cycle safety by requiring licensees to (1) perform an integrated safety analysis (ISA) to identify significant potential accidents at the facility and the items relied on for safety and (2) implement measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed. Internal staff guidance will be completed in nine ISA areas.

#### 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 PBPM process. As part of the FY 2006 PBPM process, the program offices developed a common prioritization methodology and used it to produce a prioritized listing of planned activities. The offices continued to use the common prioritization methodology to plan, budget, and implement RIRIP activities. As with other staff activities, changes in priorities of the risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities. No additional funds are required and all activities are budgeted.

#### 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.

***/RA Martin J. Virgilio Acting For/***

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

4. Risk-Inform High-Level Waste (HLW) Framework (WS-MS1-3): To support a risk-informed license application review, the staff will continue to refine the Risk Insights Baseline for the potential Yucca Mountain repository as new risk information becomes available. Currently, the staff is completing a series of focused risk analyses to strengthen the quantitative information supporting the risk insights and to better understand uncertainties in the risk insights. The staff plans to review its Risk Insights Baseline in light of the new risk information before receiving a license application from DOE.
  
5. Revise Part 70 (MS-MS2-3): The staff will continue reviewing the implementation of the upgrade to 10 CFR Part 70 Subpart H. The staff will ensure that licensees are meeting the Commission's objectives for a risk-informed and performance-based regulatory approach for fuel cycle safety by requiring licensees to (1) perform an integrated safety analysis (ISA) to identify significant potential accidents at the facility and the items relied on for safety and (2) implement measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed. Internal staff guidance will be completed in nine ISA areas.

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2. Risk-Informed Regulation Implementation Plan

OAR in ADAMS? (Y or N) Y  
 TEMPLATE NO. SECY-012  
 Publicly Available? (Y or N) Y  
 \*See previous concurrence

PACKAGE NO.: ML042670273  
 SENSITIVE? N  
 DATE OF RELEASE TO PUBLIC September 2004

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