POLICY ISSUE
INFORMATION

April 22, 2005 SECY-05-0068

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 #M001117B) dated January 4, 2001.

SUMMARY:

This paper summarizes the agency's significant risk-informing accomplishments since the previous version of the RIRIP (Attachment 1), and provides 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. The priorities of the activities included in this RIRIP update were determined through the FY 2006 planning, budgeting, and performance management (PBPM) process. All resources for this effort are budgeted in both FY 2005 and FY 2006.

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 safety and protection, acceptance criteria for emergency core cooling systems for light-water nuclear power reactors (10 CFR 50.46), special treatment requirements (10 CFR 50.69), PRA quality, new reactor licensing framework development, the reactor oversight process, dry cask storage, materials licensing guidance, steam generator performance, and pressurized thermal shock.

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BACKGROUND:

In a January 2000 memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. That strategy evolved into the initial 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 RIRIP update an internal communications plan, staff training requirements, and a discussion of internal and external factors that may impede risk-informed regulation. The staff issued the first complete version of the RIRIP in October 2000.

In the SRM dated January 4, 2001, the Commission asked the staff to provide a more detailed communication plan, prioritize activities, identify necessary resources and tools, address how performance-based regulatory approaches would be integrated into the process of risk-informing regulations, and identify critical-path activities and their crosscutting dimensions.

In response to that SRM, the staff's December 2001 update of the RIRIP (specifically Part 2) included expanded chapters describing the staff's progress in prioritizing the various implementation activities and identifying the necessary resources and tools, as well as activities that have crosscutting dimensions. In addition, the expanded chapters described activities related to communication with both internal and external stakeholders.

DISCUSSION:

In August 2004, the NRC issued its revised Strategic Plan for Fiscal Years (FY) 2004–2009. That new plan established five goals (safety, security, openness, effectiveness, and management), as well as the strategies that the agency will use to achieve each goal.

In response, the staff has restructured the RIRIP to organize future updates around the goals in the Strategic Plan for FY 2004–2009. Toward that end, this RIRIP update lists the primary and secondary performance goals (including their respective priorities) 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 Management (PBPM) common prioritization 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.

Attachment 1 to this paper is a table of accomplishments, which describes the agency's risk-informing accomplishments since the previous update of the RIRIP. Attachment 2 is the latest update of the RIRIP, which discusses the staff's activities to risk-inform the agency's regulatory activities and describes each of the activities identified as supporting the goals and strategies of the NRC's Strategic Plan and the Probabilistic Risk Assessment (PRA) Policy Statement. The updated RIRIP is divided into two parts:

- Part 1 describes the plan's relationship to the PRA Policy Statement. It also discusses key features of the traditional deterministic approach that should be preserved in establishing risk-informed regulatory programs, since the NRC will use risk information to complement the traditional approach.

- Part 2 describes the staff's risk-informed regulatory activities, with a chapter addressing activities that have "safety" as their primary goal (as defined in the NRC's Strategic Plan for FY 2004–2009) and a chapter addressing activities that have "effectiveness" as their primary goal (again as defined in the NRC's Strategic Plan for FY 2004–2009). Each chapter describes the implementation activities for each strategy and identifies significant milestones, training, and communication-related considerations for each activity. In addition, Part 2 describes relationships among implementation activities and identifies critical-path items.

The following paragraphs describe the major risk-informing activities to be conducted by the NRC over the next 6 months. These include16 of 35 activities that are discussed in the RIRIP (Attachment 2).

SAFETY (Primary FY 2004–2009 Strategic Plan Goal)

1. **Reactor Oversight Process (ROP) Support (SA-2)**: The NRC's Office of Nuclear Regulatory Research (RES) supports the ROP by developing models and guidelines for the Risk Assessment Standardization Project (RASP). The staff will use these models and guidelines to perform risk analyses of inspection findings and reactor incidents, improve coordination among various NRC programs that perform risk analyses of licensees' performance deficiencies, reduce the time required to perform risk analyses, improve the NRC's internal and external risk communications, provide solutions to technical issues surrounding risk assessments and operating events, and provide NRC risk analysts with sufficient information to assess the quality of licensees' risk analysis results. Under RASP, final guidelines for analysis of internal events during power operation are expected to be ready in April 2005, and the final guideline for the Accident Sequence Precursor (ASP) expert elicitation will be issued in June 2005.

2. **Changes to Technical Requirements of 10 CFR 50.46 (SA-8):** The Commission's March 31, 2003, SRM on SECY-02-0057 approved most of the staff recommendations on possible changes to LOCA requirements and also directed the staff to prepare a proposed rule that would provide a risk-informed alternative maximum break size. The Commission provided additional direction in an SRM dated July 1, 2004. Based on the Commission guidance, the staff has prepared a proposed rule which contains alternative emergency core cooling system (ECCS) evaluation requirements to10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems (ECCS) for Light-Water Nuclear Power Reactors." These alternative requirements would be codified in a new regulation 10 CFR 50.46a, and could be used in lieu of the requirements in the current 10 CFR 50.46. In addition, the rule could be adopted by current nuclear power reactor licensees.

   In support of the new regulation, the staff is preparing a Regulatory Guide. The staff plans to present a draft Regulatory Guide to the ACRS before the end of FY05. The proposed rule affords licensees flexibility in establishing quantitative acceptance criteria for maintenance of "coolable geometry" for breaks which are beyond the design basis, as specified in 10 CFR 50.46a. Efforts are underway to define "coolable geometry" and to estimate realistic mitigative capability.

The draft NUREG Report, “Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process,” provides preliminary LOCA frequency estimates which have been developed using an expert elicitation process to consolidate service history data and insights from probabilistic fracture mechanics (PFM) studies with the knowledge of plant design, operation, and material performance. The tentative release date for public comment is April 2005.

In an SRM, dated March 31, 2003, the Commission also directed the staff to pursue "a broader change to the single failure criterion" (broader than just the relaxation of the requirement to be able to mitigate a large break loss-of-coolant accident coincident with loss of offsite power with an additional single failure) and inform the Commission of its findings. In response to this SRM, the staff is developing a SECY paper and associated technical report which is expected to be completed in July 2005. This SECY paper will present the results of the staff’s technical review regarding the broader change to the single-failure criterion.

3. **Risk Management of Technical Specifications (RMTS) (SA-10)**: 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 as follows:

- Initiative 1, “Modified End States”: This initiative would allow (after a risk assessment) some equipment to be repaired during hot shutdown rather than cold shutdown. The staff has issued the safety evaluation reports (SERs) for the Combustion Engineering Owners Group (CEOG) and Boiling-Water Reactor Owners Group (BWROG) topical reports, and industry has proposed technical specification changes, which are under staff review. Completion of staff review of Technical Specification Task Force (TSTF)-422 for CE plants and TSTF-423 for BWR plants are scheduled for July 2005 and August 2005, respectively. In addition, the TSTFs will be available via the Consolidated Line Item Improvement Process (CLIIP).
- 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. Completion of review of a methodology document, the Limerick pilot plant license amendment, and TSTF-425 are planned for October 2005.
- 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 Limiting Condition for Operation (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 soon, and completion of staff review is planned for July 2005.
- 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 attributable to a 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 May 2005. The safety evaluation for TSTF-427 is scheduled to be issued in October 2005.

4. **Fire Protection for Nuclear Power Plants (SA-11)**: 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 into 10 CFR Part 50 was published in the *Federal Register* in June 2004. The staff is working with the industry to develop implementing guidance (NEI 04-02) for 10 CFR 50.48(c), which the NRC will endorse in a new regulatory guide that the staff expects to issue in July 2005.

5. **Methods for Calculating Risk in Support of Risk-Informed Regulatory Decision-Making (SA-13)**: The adequacy of available data for human reliability analysis (HRA) is a concern expressed by practitioners and decision-makers. Furthermore, NRC activities supported by human factors (HF) research are constrained by the lack of a database from which analysts could draw when addressing various regulatory issues. To address this need, the staff is developing a Human Event Repository and Analysis (HERA) database. Previous efforts 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 developing quantification processes that would allow the use of such data to estimate human failure event probabilities. The HERA data collection and coding activity is closely coordinated with the component database, known as the "Integrated Data Collection and Coding System." Publication of the draft contractor-prepared NUREG-series report, entitled "Human Event Reliability Analysis," is scheduled for September 2005.

6. **Materials Licensing Guidance Consolidation and Revision (SA-16):** In FY 2001, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS), Division of Industrial and Medical Nuclear Safety (IMNS), completed Phase I of its of licensing guidance consolidation with the final publication of 20 volumes of NUREG-1556, "Consolidated Guidance about Materials Licenses." Since that time, the staff has revised Volumes 1 and 3 of NUREG-1556. The staff will periodically review and revise the remaining volumes of NUREG-1556, as needed. These revisions will incorporate the recommendations from the Phase II report (issued in August 2001) from the Multi-Phase Review of the Byproduct Materials Program. (Phase II is a broad review of the entire materials program, while Phase I focused on lessons learned from the overexposure events at the Mallinckrodt facility and a radiopharmacy.) The future revisions will also integrate risk information contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems." The staff is scheduled to complete its review and revision of the following volumes of NUREG-1556 in FY 2005:

Vol. 8 Exempt Distribution Licenses (Summer 2005)
Vol. 9 Medical Use Licenses (August 2005)
Vol. 20 Administrative Licensing Procedures (September 2005)

7. **Implementation of Part 70 (Domestic Licensing of Special Nuclear Material) Revision (SA-17):** On September 18, 2000 (65 FR 56211), the Commission published a final rule (Part 70) amending its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a "Petition for Rulemaking," PRM-70-7, submitted by the Nuclear Energy Institute, which was published on November 26, 1996 (61 FR 60057). The majority of the modifications to Part 70 are included in a new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These modifications were made to increase confidence in the margin of safety at the facilities affected by the rule, while reducing unnecessary regulatory burden, where appropriate.

   In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach 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.

   The staff will continue reviewing licensees' implementations of the upgrade to Subpart H of 10 CFR Part 70. In particular, 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 and the items on which the facility relies 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.

   In FY 2004, the staff began conducting ISA summary reviews for individual amendment requests, certain existing and new processes, and a new centrifuge enrichment license application. The staff has initiated reviews of site-wide ISA summaries from the six operating uranium fuel fabrication facilities. These will continue through FY 2005–2006.

   Additionally, the staff has initiated efforts to risk-inform the inspection guidance for 10 CFR Part 70 licensees. In particular, the staff is upgrading its inspection procedures for Category I and III facilities to reduce inspection duplication and allocate time spent on each procedure based on risk-significance. The procedures focus on risk-significant activities for headquarters and regional inspectors and provide guidance for inspectors on the appropriate risk-significant items to evaluate in a licensee's program. In FY 2005, the staff will continue its efforts to risk-inform similar guidance for inspections of gaseous diffusion plants.

EFFECTIVENESS (Primary FY 2004–2009 Strategic Plan Goal)

1. **Develop PRA Standards and Related Guidance with National Standards Committees and Industry Organizations (EF-2)**: Based on the staff's comments in Appendices A, B, and C to Regulatory Guide (RG)1.200, the American Society of Mechanical Engineers (ASME), the Nuclear Energy Institute (NEI), and the American Nuclear Society (ANS) are revising and updating their respective standards and guidance documents. ASME is issuing Addendum B to the Level 1/Large Early Release Frequency (LERF) PRA standard for full-power and internal events (excluding internal fire). NEI is issuing an update

to its peer review guidance ,which includes a self-assessment process in September 2005. ANS is issuing Revision 1 to its external hazards PRA standard in June 2005.

2. **PRA Quality (EF-2)**: 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. For Phase 2, the scope of the PRA required is a function of the decision to be made (e.g., 50.69, AOT extensions.) By the end of FY 2005, the staff expects to complete development of a process for staff review of PRA technical acceptability for application-specific risk-informed submittals (RG 1.200).

3. **Pressurized Thermal Shock Rule Revision (EF-4):** 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)." That report documents the results of a multi-year study reevaluating the technical basis of 10 CFR 50.61. A peer review of that report has recently been completed, with the peer review group generally supporting the staff's methods, results, and recommendations. The NRC's Advisory Committee on Reactor Safeguards (ACRS) also reviewed the report, and expressed general support for the staff's PRA and probabilistic fracture mechanics (PFM) methods. However, the ACRS also requested additional information to address uncertainties in the staff's thermal-hydraulics (TH) methods. The staff met with the ACRS on March 3, 2005, to discuss possible resolutions for the TH concerns. Based on successful resolution of the ACRS concerns, RES plans to provide the PTS methods and results to NRR by June 2005 for possible use in a PTS rulemaking.

4. **Assessing Steam Generator Performance (EF-5):** 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 TH analyses that have been underway for several years. By May 2005, the staff is scheduled to apply the improved PRA model to a sample plant to calculate the frequency of containment bypass events due to SG failures induced by severe accident conditions. However, a broad reevaluation of this project is currently underway to assess the likelihood that it will be able to produce a useful quantitative result, within the limits of staff resources available for this effort. Depending upon the results of that reevaluation, the staff may modify the scope and schedule of this project.

5. **Develop Regulatory Structure for New Plant Licensing (EF-6)**: In SECY-05-0006, "Second Status Paper on the Staff's Proposed Regulatory Structure for New Plant Licensing and Update on Policy Issues Related to New Plant Licensing," dated January 7, 2005, the staff discussed its plan for issuing a working draft of a technology-neutral framework for new plant licensing to begin engaging stakeholders. This framework provides guidance and criteria for the staff to use in developing technology-neutral requirements and identifies several policy and technical issues for Commission consideration. The staff also held a public workshop on March 14–16, 2005, and is currently evaluating the stakeholder input, with the goal of providing recommendations on three issues for Commission consideration in July 2005. Specifically, the three issues include

the level of safety for new plants, how to address the risk for sites with multiple reactors, and containment functional performance requirements and criteria.

6. **Assessing Fire Safety (EF-7)**: The RES staff, in coordination with the Electric Power Research Institute (EPRI), has published draft NUREG/CR-6850 (EPRI1008239), entitled "EPRI/NRC-RES Fire PRA Methodology for Nuclear Power Facilities." That report describes a possible risk-informed, performance-based method for implementing the fire protection rule, as specified in 10 CFR 50.48(c). RES and EPRI are currently addressing public comments, and plan to submit a revised report for publication in July 2005, after meeting with the ACRS. This program has benefitted from demonstration studies at two pressurized-water reactor (PWR) pilot plants, which have provided feedback on the viability of this methodology. A licensee with a boiling-water reactor (BWR) plant also agreed to participate in these studies, and NRC and EPRI began work in May 2004 and will continue through FY 2005 and into FY 2006.

   Also in support of 10 CFR 50.48(c) implementation, the RES staff, in coordination with EPRI is performing verification and validation (V&V) of five fire models. Four of the five fire model V&V documents are expected to be available for public comment in April 2005. The fifth one is expected to be available 2 months later.

7. **Methods for Calculating Risk: Development of Human Reliability Analysis (EF-9)**: In July 2004, the staff issued draft NUREG-1792, "Good Practices for Implementing Human Reliability Analysis (HRA)," for public comment. The HRA good practices were developed as part of the NRC's activities to address PRA quality issues and provide guidance for implementing RG 1.200. NUREG-1792 provides a technical basis for performing an HRA or formulating questions to evaluate the quality of an HRA. The staff is currently revising NUREG-1792 to address public comments; the final report is scheduled for publication in April 2005.

8. **Probabilistic Risk Assessment of Dry Cask Storage Systems (EF-16):** In support of the Commission's policies on risk-informing the regulatory process and performance goals, the staff is currently developing PRA methods and quantifying the risk associated with dry storage of spent nuclear fuel. These studies (Phases I and II) are intended to result in (a) methods to quantify the risk of dry cask storage of spent nuclear fuel, (b) insights into decision-making and how to improve regulatory activities associated with 10 CFR Part 72, and (c) analytical tools that can be used to implement future waste safety goals and risk-informed regulatory activities. RES recently revised the draft pilot PRA of dry cask storage with a specific cask design. The staff plans to discuss this study with the joint ACRS/Advisory Committee on Nuclear Waste (ACNW) subcommittee in April 2005 and will subsequently issue the draft study for public comment in August 2005.

9. **Develop an Alternative Risk-Informed Approach to Special Treatment Requirements in 10 CFR Part 50 on the Basis of Safety-Significance Using a Risk-Informed Categorization Method (EF-18)**: In 1998, the Commission decided to consider promulgating new regulations that would provide an alternative risk-informed approach to special treatment requirements in the current regulations for power reactors (10 CFR Part 50). A final rule, adopting a new 10 CFR 50.69, was published in the *Federal Register* on November 22, 2004 (69 FR 68008). Regulatory Guide (RG) 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power

Plants According to Their Safety Significance," providing guidance on the implementation of 10 CFR 50.69, will be issued by June 2005.

RESOURCES:

In response to the Commission's direction regarding the October 2000 version of the RIRIP, the updated plan lists the priority rating of each risk-informed regulation implementation activity. These priorities were determined through the FY 2006 PBPM process, through which the program offices developed a common prioritization methodology, which they used to derive a prioritized listing of planned activities. (The "common prioritization" methodology is being changed as part of the FY 2007 PBPM process. Therefore, in order to eliminate any confusion as to whether high or low numbers indicate higher priority, the updated plan specifies goal priorities as "high," "medium," or "low.") The offices continued to use the common prioritization methodology to plan, budget, and implement RIRIP activities. As with other staff activities, the staff will continue to adjust the priorities of the risk-informed regulation implementation activities, consistent with the PBPM process, to reflect changes in the agency's budget and priorities. All resources for this effort are budgeted in both FY 2005 and FY 2006. In addition, all future resource requirements for this Plan will be obtained via the PBPM process, such as for FY 2007 and beyond.

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/ original signed by William F. Kane for
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Attachments: 1. Table of Accomplishments
2. Risk-Informed Regulation Implementation Plan

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