

POLICY ISSUE INFORMATION

October 28, 2005

SECY-05-0199

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 the 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 2007 planning, budgeting, and performance management (PBPM) process. The resources for these activities are budgeted in 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 reactor oversight process and support; risk management of technical specifications – including activities related to modified end states; fire protection and safety – including fire model verification and validation; methods for calculating risk; materials licensing guidance; domestic licensing of special nuclear material; steam generator performance; PRA quality and standards; pressurized thermal shock; advanced reactor PRA; dry cask storage; risk-informed revision of Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50); and changes to the requirements for emergency core cooling systems for light-water nuclear power reactors (10 CFR 50.46) – including “a broader change to the single-failure criterion.”

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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 directed 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:

The RIRIP is structured around the five goals of the NRC's Strategic Plan for FY 2004–2009: safety, security, openness, effectiveness, and management. 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 2007.

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 selected milestones, training, and communications-related considerations for each activity.

The following paragraphs highlight the major risk-informing activities to be conducted by the NRC over the next 6 months. These depict 15 of the 37 activities in the RIRIP (Attachment 2) - 7 related to "safety" and 8 related to "effectiveness."

SAFETY (Primary FY 2004–2009 Strategic Plan Goal)

1. **Reactor Oversight Process (ROP) (SA-1):** The Reactor Oversight Process (ROP) was developed to monitor licensee performance with respect to reactor safety, radiation safety, and security cornerstones. Performance is assessed by categorizing the indicators and inspection findings using significance thresholds to decide on agency response. The Significance Determination Process (SDP) [NRC Inspection Manual Chapter (IMC) 0609] is used for this purpose.

One of the tools used during Phase 2 of this assessment is the set of risk-informed SDP notebooks. An effort to standardize and address major changes in a licensee's PRA, and incorporate large early release frequency (LERF) risk aspects in all 71 plant-specific notebooks is scheduled to be completed in October 2005. To assist inspectors during evaluation of inspection findings, pre-solved tables (spreadsheets) for approximately 40 to 50 plant-specific key components and operator actions are scheduled to be completed for each notebook in December 2005.

2. **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 planned activities in this area are summarized below:
 - 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 safety evaluation report for the Babcock & Wilcox (B&W) topical report is scheduled to be issued in February 2006. The Technical Specification Task Force (TSTF)-423 for boiling-water reactor (BWR) plants is scheduled to be completed in December 2005 and will be made available via the Consolidated Line Item Improvement Process (CLIIP).
 - Initiative 6, "Modification of Limiting Condition for Operation (LCO) 3.0.3, 'Actions and Completion Times'": Combustion Engineering TSTF-426 safety evaluation will be published in the *Federal Register*, requesting public comment, as part of the CLIIP in December 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 technical specifications. For example, 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 TSTF-372 was made available via the CLIIP in May 2005. The safety evaluation for TSTF-427 is scheduled to be issued in October 2005 and TSTF-427 is scheduled to be made available via CLIIP in December 2005.

3. **Fire Protection for Nuclear Power Plants (SA-11):** The staff issued Regulatory Issue Summary (RIS) 2004-03 on March 2, 2004, to discuss risk-informing the post-fire safe-shutdown electrical circuit inspection process. The staff revised the inspection procedure, and held another public workshop in October 2004 to discuss how the post-fire safe-shutdown circuit analysis inspections will be risk-informed. In December 2004, a revision to RIS 2004-03, which included the risk-informed inspection process and notification that circuit inspections would resume in January 2005, was issued. Subsequently, the staff issued a second RIS for public comment in May 2005 to clarify compliance expectations with regard to circuits.

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 -- 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 04-01, Revision 1) for 10 CFR 50.48(c), which the NRC will endorse in a new regulatory guide scheduled to be issued in April 2006.

4. **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 PRA 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 report, entitled "Human Event Reliability Analysis," occurred in September 2005, and publication of Volume 1 of the HERA framework is scheduled for March 2006.
5. **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 licensing guidance consolidation with the final publication of 20 volumes of NUREG-1556, "Consolidated Guidance about Materials Licenses." The staff will periodically review and revise various 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.) 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 Volume 2 -- Program-Specific Guidance About

Radiography Licenses – in February 2006. The draft revision to Volume 8 - Exempt Distribution Licenses - is also scheduled to be completed in February 2006.

6. 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.

7. Assessing Performance of Steam Generator Tubes and Other Reactor Coolant System (RCS) Components During Severe Accidents (SA-18):

The staff is developing an improved PRA model for use in determining the frequency of pressurized-water reactor (PWR) containment bypass events that result from steam generator tube (SGT) failures induced by severe accident conditions. This work utilizes PRA, thermal-hydraulic analyses, and analyses of SGT and non-SGT RCS components. The staff has recently developed a prototype risk-informed model and has used this model to perform a preliminary evaluation of a sample Westinghouse 4-Loop plant to calculate the frequency of severe accident containment bypass events attributable to SGT failures at that plant. The staff is currently evaluating the prototype model and the results of its application to the sample plant to determine the nature and extent of expansions and improvements needed in the model. Based on the results of that evaluation, the staff will determine the scope and schedule for the remainder of this project. This planning effort should be completed in the first quarter of FY 2006.

EFFECTIVENESS (Primary FY 2004–2009 Strategic Plan Goal)

1. **Develop PRA Standards and Related Guidance with National Standards Committees and Industry Organizations (EF-2):** The increased use of PRAs in the NRC's regulatory decision-making process of the NRC requires consistency in the quality, scope, methodology, and data used in such analyses. These requirements apply to PRAs developed by industry to support risk-informed licensing actions, as well as PRAs developed by NRC staff to analyze technical issues or to support Commission decisions. To achieve this objective, professional societies, industry, and the staff have undertaken initiatives to establish consensus standards and guidance on the use of PRA in regulatory decision-making. Based on staff comments documented in Draft Regulatory Guide DG-1138 – (Draft Appendix C, "NRC Staff Regulatory Position on ANS External Hazards PRA Standard" to Regulatory Guide 1.200), the American Nuclear society (ANS) will be issuing a revision to that standard – "ANS External Events Probabilistic Risk Assessment (PRA) Methodology Standard" (BSR/ANS 58.21) – in January 2006.
2. **Pressurized Thermal Shock Rule Revision (EF-4):** In December 2002, the NRC's Office of Nuclear Regulatory Research (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. RES is currently providing briefings for NRR to support a pending decision regarding whether or not to initiate a PTS rulemaking process. A final report on the recommended changes associated with PTS screening criteria is scheduled to be transmitted to NRR in December 2005.
3. **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." This report describes a possible risk-informed, performance-based method for implementing the fire protection rule, as specified in 10 CFR 50.48(c). This program has derived benefit 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; NRC and EPRI began work in May 2004 and will continue this effort into FY 2006. RES is continuing work on fire model verification and validation documents and expects to issue them for public comment in October 2005.

Also in support of 10 CFR 50.48(c), the staff expects to complete the PRA review guidance on fire safety for NRR specialists. This guidance, which endorses NFPA 805, will be issued in December 2005. Issuance of a draft ANS fire PRA standard – for public comment – is also planned for December 2005.

4. **PRA Review of Advanced Reactor Applications (EF-10):** The staff has developed a PRA plan for the development of methods, data, and tools needed for reactor-specific PRAs to support the evaluation of the design and operational characteristics of advanced reactors that are different from those of current reactors. The PRA plan considers such things as the quantification of initiating events, likely accident phenomena, accident progression, containment/confinement performance, passive systems, digital instrumentation and control systems, uncertainties, internal flooding, external events (fires and seismic events), and multiple reactor modules on a site. Work is continuing on the generic PRA aspects for advanced reactors, as well as on design-specific reviews (e.g., economic and simplified boiling-water reactor - ESBWR). Although no additional work is being planned, a report documenting all PRA work completed to date on the ACR-700 is expected to be issued in October 2005. The draft data collection and analysis report in support of advanced reactor PRA reviews will be completed by November 2005. A report on PRA modeling of an ESBWR passive system is expected to be completed by February 2006.
5. **Probabilistic Risk Assessment of Dry Cask Storage Systems (EF-14):** 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 cask 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 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 for a specific cask design. The staff plans to present the results of the final pilot PRA to the joint ACRS/Advisory Committee on Nuclear Waste (ACNW) subcommittee by the end of the first quarter of calendar year 2006, and to issue the final pilot PRA as a NUREG-series report approximately 6 months thereafter.
6. **Risk-informed and Performance-Based Revision to 10 CFR Part 50 (EF-19):** In an SRM, dated May 9, 2005, the Commission directed the staff "to develop a formal program plan to make a risk-informed and performance-based revision to 10 CFR Part 50, including revisions to the applicable regulatory guides, standard review plans, or other guidance documents." The staff has developed a preliminary program plan and held a public meeting in August 2005 to solicit stakeholder input. The staff will provide the plan to the Commission for approval in December 2005.
7. **Reactor Oversight Process (ROP) Support (EF-20):** 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, guidelines for analysis of internal flooding events during power operation are expected to be ready in December 2005.

8. **Changes to Technical Requirements of 10 CFR 50.46 (EF-22):** The Commission's SRM on SECY-02-0057, dated March 31, 2003, approved most of the staff recommendations on possible changes to loss-of-coolant accident (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 Commission guidance, the staff has prepared a proposed rule which contains alternative emergency core cooling system (ECCS) evaluation requirements to 10 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 by current nuclear power reactor licensees. On July 29, 2005, the Commission approved publication of the proposed rulemaking subject to comments and specific changes provided in the SRM. The Commission directed that the proposed rule be issued for public comment by October 28, 2005.

In support of the new regulation, the staff is preparing a draft regulatory guide, which the staff plans to present to the ACRS by the end of March 2006. The proposed rule affords licensees flexibility in establishing quantitative acceptance criteria for maintenance of "coolable geometry" for breaks that 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-1829, "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. NUREG-1829, was issued for public comment in June 2005. Over the next several months, the staff will address both staff and public comments and make recommended changes in preparation for publication in early calendar year 2006.

The activities related to the LOCA elicitation were focused on estimating the pipe break frequency arising from routine operational events. More recently, concerns have arisen regarding the effect of seismic events on these frequency estimates, and their possible impact on the proposed rule that is currently under consideration. The staff and their contractors are currently engaged in a study to quantify the effects of seismic hazards on pipe break frequencies. It is anticipated that the results of this study will be made available for public comment in December 2005.

In the SRM, March 31, 2003, the Commission also directed the staff to pursue "a broader change to the single failure criterion" and inform the Commission of its findings. In response to this SRM, the staff developed a Commission paper and associated technical report. The Commission paper, entitled, "Risk-Informed and Performance-Based Alternatives to the Single Failure Criterion," issued in August 2005, presents the results of the staff's technical review regarding the broader change to the single-failure criterion. The paper did not include a recommendation for any specific option, but it did suggest further study specifically aimed at obtaining more stakeholder feedback.

In an SRM, dated September 21, 2005, the Commission directed the staff to seek additional stakeholder involvement by making the draft technical report on the single-failure criterion available to the public. The Commission also directed the staff to develop expeditiously an Advanced Notice of Proposed Rulemaking (ANPR) to consider the spectrum of issues relating to risk-informing the reactor requirements, including the effort to develop risk-informed and performance-based alternatives to the single failure criterion.

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 2007 PBPM process, according to a common prioritization methodology developed by the program offices and used to derive a prioritized listing of planned activities. Resources for RIRIP activities – except those activities noted as being deferred (i.e., "on hold") – have been budgeted in FY 2006. In addition, future resources needed for RIRIP activities will be obtained through the PBPM process.

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/

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

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DOCUMENT NAME: E:\Filenet\ML052620538.wpd Package: ML

OAR in ADAMS? Y

ADAMS Accession No.: PKG ML052620458

Template No. SECY-012

Publicly Available? Y

Date of Release to Public _____

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