

POLICY ISSUE INFORMATION

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SECY-02-0131

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 an updated and revised version of the Risk-Informed Regulation Implementation Plan (RIRIP) and to respond to the staff requirements memorandum (SRM) dated February 8, 2002, regarding the “convergence” of risk-informed activities pertaining to reactor safety. This paper also provides a summary of public PRA Steering Committee meetings held since December 2001.

SUMMARY:

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 is organized into two parts. Part 1 provides a general discussion of the document’s relationship to the PRA Policy Statement and the Strategic Plan. It also discusses deterministic and other elements for consideration in the process of risk-informing and provides guidance for selecting appropriate “candidates” for risk-informing. Part 2 describes the staff’s ongoing risk-informed regulation activities in the reactor safety arena and the waste safety and materials safety arenas.

The Agency’s accomplishments in risk-informing its regulatory activities since December 2001 are described in Attachment 1. Key risk-informing activities to be conducted at the Agency over the next 6 months are described in the paragraphs below.

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Reactor Safety Arena

1. Option 2 (Special Treatment Requirements): The staff is continuing to work on the statement of considerations and other parts of a proposed rule package. Draft Revision C of the industry guidance document, NEI 00-04, was submitted to the NRC in a letter dated June 28, 2002. The staff plans to complete a draft regulatory guide endorsing this document (with clarification if needed) as part of the proposed rule package. The staff will meet with ACRS in September to discuss the proposed rule and guidance. The current schedule is to forward the proposed rule to the Commission in September 2002.
2. Option 3 (Risk-Informing Part 50)
 - ▶ Hydrogen Control Requirements (10 CFR 50.44): On June 27, 2002, the Commission approved the proposed rulemaking package. The staff is in the process of publishing the proposed rule in the *Federal Register*.
 - ▶ ECCS Acceptance Criteria (10 CFR 50.46): The staff has recommended that separate rulemakings be pursued for proposed changes to ECCS reliability requirements, ECCS acceptance criteria, and ECCS evaluation model requirements. An initial draft report on the approach for modifying the ECCS reliability requirements was completed in May 2002. The final version of this report will be completed in July 2002, as will as reports on the technical bases to support rulemaking for the proposed changes to the ECCS acceptance criteria and evaluation model requirements.
1. In December 2001, the staff posted draft language for a proposed risk-informed and performance-based fire protection rule on the NRC rulemaking website for public review and comment. Comments received through the website were considered in preparing the proposed rule language. The staff gave presentations to the Advisory Committee on Reactor Safeguards the week of June 2, 2002, and the Committee to Review Generic Requirements the week of June 9, 2002. A letter supporting the staff's rulemaking effort was issued by the ACRS on June 17, 2002. The proposed rule will be provided to the Commission in July 2002.
2. In response to a Commission SRM of February 8, 2002, the staff is developing a plan for improving coherence among risk-informed activities. The goals of this plan are to develop a common understanding of risk-informed regulatory objectives and to obtain staff and stakeholder buy-in of the objectives. The plan has five elements: (1) define the problem, (2) develop a structured, systematic framework, (3) develop the desired characteristics of an integrated risk-informed regulatory structure, (4) identify and evaluate risk-informed activities, and (5) prioritize and modify activities, as appropriate. Each part of the plan will take advantage of and build on ongoing staff activities. The staff expects to hold several public meetings and workshops during the next few months and to develop a detailed plan by early fall.
3. In April 2002, NRR completed the first phase of the Risk-Informed Environment initiative. The staff and its contractors have evaluated information collected in the focus groups and interviews and identified the following key challenges to creating an improved environment for risk-informed regulation:
 - ▶ create a shared vision of "risk-informed" and "integrated decisionmaking"

- ▶ integrate PRA roles and responsibilities more deeply into the organization
- ▶ improve the knowledge and experience levels within the Office
- ▶ improve communication channels among staff and between staff and management
- ▶ correct misconceptions about PRA technology

The detailed results of the first phase will be shared with the staff. In addition, in conjunction with the coherence initiative, the staff will develop a plan identifying ways of meeting the challenges within the broad areas of communication and information, training, and process improvement.

4. The staff continues to work on numerous risk-informed technical specification initiatives. The safety evaluations for Initiative 1, Technical Specification Actions End State Modifications, and Initiative 3, Modification of Mode Restraint Requirements, will be completed within the next 6 months.
5. The staff is continuing its work to develop a regulatory guide and a Standard Review Plan (SRP) chapter to assess PRA adequacy. The staff expects to have completed the regulatory guide and SRP chapter by December 2002, as well as Appendices A (staff position on the ASME PRA standard on internal events) and B (staff position on the NEI PRA review guidance on internal events).
6. The staff is assessing the need for changes to the pressurized thermal shock (PTS) rule (10 CFR 50.61). Over the remainder of 2002, the staff will continue its activities to identify PTS-related accident sequences; integrate the results of supporting analyses to calculate the frequency of vessel failure and core damage; recommend changes to operational limits associated with PTS acceptance criteria; and assess the need for PTS rule changes and provide recommendations.

Waste Safety and Materials Safety Arenas

1. The final rule amending the regulations regarding the medical use of byproduct material (10 CFR Part 35) becomes effective on October 24, 2002 (67 FR 20249). The final rule is one component of the Commission's program for revising its medical use regulatory framework to focus the regulations on high-risk medical procedures and to make its regulations more risk-informed and more performance-based. Prior to the effective date, staff will complete other elements of the program, including the revision of NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses," and the revision of four medical inspection procedures to reflect final rule changes to 10 CFR Part 35. Training will also be conducted for licensing and inspection staff and will be made available to staff in Agreement States.
2. The staff anticipates the issuance of a final rule in September 2002 to amend the regulations governing the disposal of high-level radioactive wastes at Yucca Mountain to define the term "unlikely" in quantitative terms. The term will be defined as a range of numerical values to determine whether a feature, event, or process, or a sequence of events and processes, should be excluded from certain required assessments.

3. As part of the effort to make the fuel cycle oversight program more risk-informed and performance-based, the staff plans to complete the revision of Inspection Manual Chapter 2600, "Fuel Cycle Facility Operational Safety and Safeguards Inspection Program," by October 2002.
4. The staff is currently reviewing and consolidating all decommissioning policy and guidance documents to support the use of efficient and risk-informed approaches by staff and licensees. During the next 6 months, the staff intends to complete the final version of Volume 1 of a three-volume NUREG report documenting the policy and guidance and to release Volumes 2 and 3 for public comment.

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 gave 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 that the staff provide a more detailed communication plan to better highlight the Agency's goal of improving public confidence, prioritize activities, identify necessary resources and tools, address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations, and identify critical-path activities and those that have cross cutting 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 cross cutting 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 and additions to the activity descriptions. Several new risk-informed activities have been initiated since the December 2001 RIRIP was issued. These include two new reactor safety arena activities and six new activities in the materials safety and waste safety arenas. The new reactor arena activities are (1) a strategy to improve coherence among risk-informed activities in the reactor arena (see discussion below), and (2) the development of a regulatory guide and SRP to assess PRA adequacy for decisionmaking (see Part 2, Chapter 1, Activity RS-EER1-8). The discussion of the first activity responds to the Commission's SRM of February 2002, as discussed below.

There are six new activities in the materials and waste safety arenas: (1) develop a guide for performing risk analyses, (2) develop safety goals for the materials and waste safety arenas, (3) evaluate low-level source material containing low levels of thorium and/or uranium, (4) evaluate byproduct materials exemptions, (5) amend Part 63, and (6) do a cross cutting risk assessment of spent fuel management. These new activities are discussed in detail in Part 2, Chapter 2, of the plan.

DISCUSSION

Over the past few years, the staff has made significant progress toward risk-informing its regulatory activities. Attachment 1 to this Commission paper summarizes the staff's significant accomplishments since publication of the December 2001 RIRIP. While the staff has made considerable progress, work remains to be done. Using the Probabilistic Risk Assessment (PRA) Policy Statement and the NRC's Strategic Plan as a foundation, the RIRIP describes activities that are planned and underway and the interrelationships among the activities.

Plan for Improving Coherence Among Reactor Arena Risk-Informed Activities

Although a great deal of progress has been made towards risk-informing regulatory activities, the staff is aware that many existing regulations remain inconsistent (or incoherent) with risk-informed practices. Many NRC regulations and processes have evolved in a less-than-integrated manner over the years. For example, the risk-informed significance determination processes used to evaluate performance deficiencies under the current reactor oversight program (ROP) have identified numerous regulations for which non-compliance is not risk-significant. In addition, since risk was not assessed when most reactor design basis regulations were promulgated, use of the risk-informed ROP emphasizes safety issues not directly addressed in licensee Final Safety Analysis Reports or other docketed material. Furthermore, research and analysis over the years has revealed that some NRC regulations are overly conservative or unnecessarily burdensome without commensurate benefits to public safety. These regulations divert licensee and NRC resources away from more safety significant issues. There may also be inconsistencies between the approaches and the objectives that the staff has used to risk-inform different activities.

Consequently, the staff has been developing a program to address the coherence of regulatory activities. This program would provide an approach in which the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another. An inter-office working group has been formed and is developing a detailed action plan for the program to improve coherence among risk-informed activities. The staff intends to engage stakeholders throughout the process.

Responding to a briefing by the staff on significant issues in the reactor safety arena, the Commission stated in a February 8, 2002, SRM that, in parallel to these staff activities, "in the next version of the RIRIP, the staff should provide its plan for moving forward with risk-informed regulation to address regulatory structure convergence with our risk-informed processes."

To complete this initiative, the staff will continue to investigate why there is not a common understanding of risk-informed regulatory objectives. Next, the staff will develop an overarching approach to provide a common structure for risk-informing activities. This approach will be based on the framework previously developed for risk-informing Part 50 that was presented in SECY-00-0198 ("Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," dated September 14, 2000). The overarching approach will also utilize and expand the cornerstones developed by the reactor oversight program. The staff will use stakeholder input (such as NEI-02-02, "A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors," dated May 2002, and related work now being funded by the Department of Energy) and will also solicit additional input.

Next, the staff will determine the desired characteristics of an integrated, risk-informed regulatory structure. These characteristics will be derived from the characteristics defined in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 – 'Domestic Licensing of Production and Utilization Facilities'," dated December 23, 1998, and will be consistent with the philosophy outlined in the Commission White Paper on Risk-Informed, Performance-Based Regulation, dated March 11, 1999.

The staff then will evaluate risk-informed activities to identify inconsistencies and commonalities among activities and their desired characteristics, as noted above. We will look for safety concerns, inefficiencies, and unnecessary regulatory burden. Based on the results of the evaluation, we will set priorities and modify activities, as appropriate, so that they meet the desired characteristics. It should be noted that legitimate differences may exist among activities due to their particular purpose but that the activities should each contribute to the overarching goal of risk-informed regulation.

As noted above, the staff intends to engage stakeholders throughout the process. The detailed plan includes numerous public meetings and workshops. We will provide more details on the program to the Commission in a separate paper this fall. The staff anticipates that this paper will include a summary of its initial meetings with stakeholders and its thoughts on standardizing the terminology used in risk-informed applications and a common objective for the program.

In parallel with work to risk-inform operating reactor regulatory processes, the staff has been investigating approaches for making advanced reactor licensing more risk-informed. One part of the staff's program to improve coherence will be an assessment of whether merging this advanced reactor framework development with operating reactor process improvements will result in a more efficient and effective outcome. While the staff previously planned to develop a paper to discuss an alternative regulatory framework for advanced reactor designs [SECY-01-088/WITS 200100109], the staff believes that it should be discussed in a future SECY, following the assessment. It is not yet clear that this will be the case because of a number of policy and technical issues unique to some advanced reactor design reviews. However, the staff is starting with the idea that a single, top-down approach is best, where differences between advanced reactors and operating reactors are addressed at a lower level in the framework. Some of these policy issues (e. g., whether current risk metrics are sufficient for all advanced reactor designs) are the subject of a future Commission paper.

PRA Steering Committee: Summary of Public Meetings

Since December 2001, the PRA Steering Committee (PRA SC) has held two public meetings to discuss ongoing efforts to risk-inform NRC regulatory activities. The NRC and the Nuclear Energy Institute (NEI) were the main participants in discussions at the meetings. Key topics of discussion are listed below.

PRA SC public meeting, December 4, 2001: Key items discussed included the PRA SC charter, status of Option 3 issues (50.44 rule language, decay heat petition status, LOOP/LOCA, and 50.46 progress), status of RISC 3 treatment under Option 2, PRA standards development (ASME standard, RG 1.174), and progress on risk-informing technical specifications. The charter was discussed as a means of clarifying the PRA SC's mission to NEI.

PRA SC public meeting, April 24, 2002: Key items included Option 3 issues (general status, LOOP/LOCA redefinition, ECCS) and general direction or focus for Option 3. With regard to

the latter, NEI indicated that existing projects should be completed before new research activities are begun. Other items discussed included RISC-3 SSCs rule language, risk-management technical specifications (formerly "risk-informed" technical specifications), and PRA standards development.

RIRIP Content and Organization

Part 1 of the RIRIP (Attachment 2) 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.

To complete the plan, Part 2 of the RIRIP describes the staff's risk-informed regulation activities, with chapters addressing the nuclear reactor safety arena and the nuclear 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(s). In addition, each chapter describes the implementation activities for each strategy and identifies significant milestones and training and communications considerations for each activity. Budgetary resources for each implementation activity are shown for Fiscal Year 2002 (as well as FY 2001 for some reactor activities). Relationships among implementation activities are described and critical path items are identified. Gantt charts for each implementation activity are also provided to illustrate the relationships among tasks within activities.

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 and the FY 2002 resources listed in the plan have been budgeted by NRR, NMSS, and RES, consistent with their respective operating plans. The offices have different prioritization processes; however, each office uses the performance goals defined in the Agency's Strategic Plan to prioritize office activities as part of the budget process. 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.

/RA/

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

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