

## **POLICY ISSUE** **(Information)**

December 5, 2001

SECY-01-0218

FOR: The Commissioners

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SUBJECT: UPDATE OF THE RISK-INFORMED REGULATION IMPLEMENTATION  
PLAN

### PURPOSE:

To give the Commission an updated and revised version of the Risk-Informed Regulation Implementation Plan (RIRIP), and to inform the Commission of the staff's plans to improve the process for planning the various activities associated with risk-informed regulation.

### SUMMARY

The RIRIP discusses the Agency's efforts 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 elements for consideration in the process of risk-informing and provides guidance for selecting appropriate "candidates" for risk-informing. Part 2 describes each of the staff's ongoing risk-informed regulation activities, which are organized by reactor arena and waste/materials safety arenas. The arena chapters in this issue of the RIRIP have been modified in response to the Commission's direction. Specific modifications are discussed later in this paper. Additionally, the plan provides each activity's relative priority rating as determined by the respective offices.

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The Agency's accomplishments in risk-informing its regulatory activities over the past year are described in Attachment 1. Key risk-informing activities to be conducted at the agency over the next six months are described in the paragraphs below by arena.

#### Reactor Safety Arena:

- Option 2 - Draft rule language for Risk-Informing Special Treatment Requirements is expected to be made available for public comment early in December. The staff will meet with the Advisory Committee on Reactor Safeguards in December to discuss the draft rule language and other related matters. Pilot plant activities continue with staff observation of the categorization process at Wolf Creek in October and plans for observation at Surry in January, 2002. The staff is continuing to work on the statement of considerations, regulatory analysis and environmental assessment to support this proposed rule. The proposed rule will be submitted to the Commission in April 2002.
- Option 3 - On November 14, 2001, a draft rule language package for combustible gas control was made available for public review and comment on the NRC rulemaking web site. The comment period is expected to run through the end of December 2001. The proposed rule will be submitted to the Commission by January 31, 2002.
- 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 six months.

#### Waste Safety and Materials Safety Arenas:

- NMSS will issue final Screening Considerations and Implementation Guidance for identifying NMSS regulatory activities that may be amenable to increased use of risk insights (i.e., to being risk-informed). These documents will be issued in March 2002.
- NMSS will review its regulatory activities and apply Screening Considerations to identify specific, high-priority areas that may be amenable to being risk-informed in the near-term and long-term. It will also develop draft safety goals that may be used to direct and promote consistency among NMSS risk-informed initiatives and activities. These activities will be completed in March 2002.
- The risk-informed revision to Inspection Manual Chapter 2604, Licensee Performance Review will be completed in March 2002.
- The risk-informed Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility (NUREG-1520) will be completed in December 2001.
- During the next six months RES will complete the following tasks for the dry cask storage PRA project: analyses of thermal and mechanical loads on the cask following postulated accidents, human reliability analysis on probability of cask drop during lifting and transfer of the cask, and source term and consequence analyses. Results of these tasks will be used as input into an integrated dry cask PRA model. RES will run the integrated PRA model to come up with an overall risk assessment and to identify the

dominant risk contributors for the dry cask storage system. RES will provide a draft report to NMSS with the results of this assessment in June 2002.

## BACKGROUND

In a January 2000 memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. That strategy evolved into an 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, issued in October 2000, was intended to integrate the staff's risk-informed activities and include the supplementary material that the Commission requested in April 2000.

The staff briefed the Commission on the RIRIP on November 17, 2000. Subsequently, in a staff requirements memorandum (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 the activities, identify the necessary resources and tools, address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations, and identify the critical path activities and those that have cross-cutting dimensions.

In response to the SRM this update of the RIRIP, specifically Part 2, features 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 those that have cross-cutting dimensions. The arena chapters also describe arena-specific activities related to communication with both internal and external stakeholders.

## DISCUSSION

In 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 the October 2000 RIRIP. While the staff has made considerable progress, more work remains to be done. Using the Probabilistic Risk Assessment (PRA) Policy Statement and the NRC's Strategic Plan as its foundation, the RIRIP describes activities that are planned and underway, and describes the interrelationships among these activities.

### Prioritization of Risk-Informed Regulation Activities

The agency has implemented a planning, budgeting, and performance management (PBPM) process, which the staff has used to prioritize, plan, budget and manage the risk-informed regulation activities described in the RIRIP. The staff has also made much progress in identifying, planning, and implementing risk-informed activities. Given this experience, the staff recognizes that the breadth and complexity of initiatives associated with risk-informed regulation require careful planning and coordination. Therefore, the staff intends to continue to

support the PBPM process through integrated planning of risk-informed activities. In addition, the staff will continue, and where necessary initiate, activities to:

- articulate and propose clear and consistent statements of the vision for risk-informed regulation
- develop and propose criteria for judging whether activities to risk-inform regulation are proceeding in a successful manner
- discuss the programs that are intended to risk-inform regulation, and assess whether they are both necessary and sufficient to accomplish the stated goals
- identify new programs and recommend changes to existing programs for applying risk information in the regulatory decision making process
- develop arena-specific communication plans related to implementing risk-informed regulation to support the NRC's performance goal to increase public confidence
- facilitate the availability and understandability of risk assessment models and data to the interested public

The staff will work within the line organization and the PRA Steering Committee, and the appropriate arena management will use the PBPM process to implement changes to the staff's activities. To facilitate information exchange on technical and project management issues, staff and management will closely coordinate activities within the reactor safety arena with the line organizations and oversight groups in the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) that are responsible for managing activities in the materials safety and waste safety arenas (i.e., the NMSS Risk Task Group and NMSS Risk Steering Committee).

In the course of its planning and review activities, the staff may identify needed additions and/or modifications to the NRC's Strategic Plan. In such instances, the staff will follow the established process for updating the Strategic Plan.

#### Cost-Benefit Aspects of Risk-Informed Regulation for Materials Licensees

The SRM specifically indicated that the staff should carefully examine the cost-benefit aspects of risk-informed regulation for materials licensees where, in certain instances, risk-informing the process may be cost prohibitive and provide little or no additional benefit. The staff has factored cost-benefit aspects into the set of considerations that will be used to evaluate whether to risk-inform particular nuclear materials and waste regulatory applications. The set of considerations (referred to as the draft screening criteria and discussed in Part 1 and Part 2, Chapter 2 of the RIRIP) includes four considerations addressing potential benefits of risk-informing a regulatory application, and three considerations addressing costs, feasibility, and other prohibiting factors that may negate the potential benefits. These considerations will focus the staff's attention to ensure that the staff will not pursue risk-informing regulatory applications, particularly those affecting materials licensees, that will be cost prohibitive or will provide little or no additional benefit.

Lessons Learned in Risk-Informed Regulation

In addition to making significant progress, the staff acknowledges lessons learned to-date in risk-informed regulation. In the reactor safety arena, for example, the staff acknowledges the criticism that progress toward risk-informed regulation has been uneven and incomplete, and additional work is needed to better integrate individual projects. The following highlights summarize some of the lessons learned in the reactor safety arena:

- Some important issues arose in connection with the staff's decision to grant exemptions for the South Texas Project (STP) to vary the treatment applied to systems, structures, and components on the basis of their safety significance using a risk-informed categorization method. The issues of public confidence and acceptance by internal stakeholders posed significant challenges in the initiative to develop a risk-informed approach as an alternative to the special treatment requirements Title 10, Part 50, of the *Code of Federal Regulations* in (10 CFR Part 50). The STP exemption review also highlighted the need for management to provide clear policy and guidance to facilitate the staff's implementation of risk-informed approaches. To address these challenges, the staff initiated an activity (RS-EER1-1, described in the RIRIP) to create an environment in which risk-informed methods are better integrated into the staff's guidance and activities.
- The recent staff recommendation to establish explicit equipment reliability requirements in 10 CFR 50.46 has important implications for agency decisions related to risk-informing technical specifications. In addition, the new changes to the Maintenance Rule are also key to risk-informing technical specifications. These regulations highlight the vigilance needed to ensure that agency decisions are founded on current, valid assumptions about nuclear power plant design and operation. Further, these implications illustrate the need for formal decision making processes to identify and assess such influences.
- The staff's experience in examining the technical basis for the requirements of 10 CFR 50.44 and recommending rule changes raised issues about the scope of risk-informed regulation. On an issue-specific basis, the staff may need to weigh the relative benefits of specific regulatory changes that are expected to reduce unnecessary regulatory burden while maintaining safety. This benefit assessment will help to define the extent of regulatory change that is justified and will focus the agency's limited resources on the most important regulatory changes, while continuing to account for stakeholder input.
- A clear vision of what constitutes success in risk-informed implementation activities will help to ensure that the staff's activities are balanced and consistent. For example, an articulated and shared vision of the role of the significance determination process notebooks, the Standardized Plant Analysis Risk (SPAR) models, and risk-based performance indicators in the reactor oversight process will promote coordination among these activities.
- In the interest of effectiveness and efficiency, the staff recognizes the need to integrate the application of risk-informed and performance-based approaches to regulatory change. One approach that the staff is considering is to modify the management directives associated with rulemaking to include staff guidance on performance-based and risk-informed regulatory change.

- In the next version of the RIRIP, the staff intends to incorporate process improvements for planning and coordinating risk-informed activities that are being considered to support the PBPM process as discussed above. The staff will continue to improve the plan's usefulness in integrating the agency's overall vision for implementing risk-informed activities.

The above lessons learned in the reactor safety arena are a function of the maturity and stage of risk-informed regulation in that arena. Lessons have also been learned from the initial risk-informed regulation initiatives and activities in the materials and waste safety arenas, as follows:

- NMSS is nearing the end of the eight risk-related case studies that were conducted (1) to test the usefulness and applicability of draft screening criteria, (2) to evaluate how the application of risk information has affected or could affect particular areas of the NMSS regulatory process, and (3) to draft risk metrics and safety goals. The insights gained thus far indicate the importance of looking laterally across NMSS activities when evaluating the application of risk information and comparing and contrasting regulatory, technical, and policy issues among the different regulatory activities. Also, through stakeholder interaction, the staff has identified a few modifications to the screening criteria and is evaluating whether the screening criteria should be finalized as "considerations" rather than "criteria." The staff has also found that risk metrics and goals are an essential element of risk-informing the materials and waste regulatory activities; however, it is likely that higher-level, generally applicable safety goals must be supplemented by lower-level, application-specific goals.
- The case study activities heightened the staff's awareness of the importance of both external and internal stakeholder involvement. While many external stakeholders appreciated early involvement in the process through public workshops, the staff found that some stakeholders were frustrated by the absence of decisions or conclusions. Also, the staff found that direct and active involvement of internal staff, as information resources during the case studies and as subject matter experts during the stakeholder workshops, fostered a more supportive environment for risk-informed regulation.
- In September 2000, the Commission published a risk-informed, performance-based revision to 10 CFR Part 70. Implementation of this revised rule has emphasized the importance of adequate guidance and staff training. As a result, the staff is developing a Standard Review Plan and other guidance documents that will assist licensees in conducting integrated safety analyses (ISAs) and the staff in reviewing ISA documentation. The staff is also providing in-house training on ISA methodology and review.
- The NMSS and RES staffs are currently working together to develop a model PRA for dry cask storage of spent reactor fuel. This activity demonstrates the feasibility of applying existing risk assessment methods and tools to regulatory applications that are beyond those originally targeted. In this case, the dry cask storage study will demonstrate the successful application of PRA methods and tools, developed for the reactor arena, to activities in the materials and waste arenas. Insights gained through this study may support the broader application of existing PRA and other methods and tools in the materials and waste safety arenas.

- Through Phase II of the byproduct materials program review, the staff identified the need to define risk metrics and goals before making judgements about resource allocation relative to risk reduction. Risk metrics and goals should reflect the various areas of concern for a particular materials application, and should consider avoided consequences and lowered probabilities of occurrence. The staff also determined that having risk models and data available in a dynamic system (such as a computer model or database) together with a static system (such as a published report) greatly enhances the evaluation of risk assessment results for risk management purposes. As a result, the staff is developing a training course to teach the theory and practices used in developing the “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems” (NUREG/CR-6642), as well as developing future data and the database and models to support future analyses.
- The staff found that human reliability and performance are the prevailing factors that contribute to risk and its uncertainty in radiography and irradiator risk assessments. The staff also found that a significant consideration in using risk assessment results is the determination of a permissible, or tolerable, level of risk. Without a target level of risk for judging results, the evaluation of a risk analysis may be limited to measuring the direction of the risk vector. In addition, without specified permissible levels of risk, small increases in the risk levels might not be accepted, even if the absolute value of the risk is quite small and tolerable in other industries.

### RIRIP Content and Organization

Part 1 of the October 2000 RIRIP describes its relationship to the PRA Policy Statement and its relevance to the NRC’s Strategic Plan. Part 1 of the RIRIP 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 of the RIRIP gives draft guidance on selecting “candidate” requirements, practices, and processes to risk inform.

To complete the plan, Part 2 of the October 2000 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 for each activity.

In response to the Commission’s direction, the staff has significantly modified the arena chapters in Part 2 of the RIRIP, as follows:

- Implementation activities have been added or removed to better focus on agency activities that are most directly tied to risk-informed regulation. Consequently, the implementation activities are also presented in a new order.
- Training and communication activities are explicitly described as an integral part of specific implementation activities.
- The priorities derived from the PBPM process are shown for each implementation activity.

- The performance-based aspect of regulatory change is described for some staff activities (such as 10 CFR 73.55 changes) to communicate the staff's efforts to implement the agency's performance-based regulation policy as risk-informed regulatory changes are made.
- Budgetary resources for each implementation activity are shown for Fiscal Years 2001 and 2002.
- Completion dates for major milestones are provided as a measure for tracking the extent to which the staff has met its schedules.
- Relationships among implementation activities are described and critical path items are identified.
- Gantt charts for each implementation activity have been developed to illustrate the relationships among activity tasks.

Attachment 2 presents a graphical illustration of the revised format, while Attachment 3 provides the updated version of the RIRIP.

## RESOURCES

In response to the Commission's direction regarding the October 2000 version of the RIRIP, as communicated in the SRM dated January 4, 2001, the plan lists the priority rating(s) of each risk-informed regulation implementation activity. These priorities were determined through the PBPM process, and the resources listed in the plan have been budgeted by the various offices, consistent with their respective operating plans. While NRR, NMSS, and RES management follow different prioritization processes, each 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. Layout and Format of Activity Descriptions  
3. Risk-Informed Regulation Implementation Plan



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