

## **POLICY ISSUE INFORMATION**

October 26, 2000

SECY-00-0213

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: RISK-INFORMED REGULATION IMPLEMENTATION PLAN

PURPOSE:

To give the Commission the first complete version of the Risk-Informed Regulation Implementation Plan (RIRIP) and to describe internal and external factors that may impede the implementation of the Commission's risk-informed activities.

BACKGROUND

In SECY-00-0062, the staff gave the Commission a first (incomplete) version of the RIRIP. As described in former-Chairman Jackson's letter of June 18, 1999, to Senator Thompson and others, the RIRIP was developed in response to a General Accounting Office (GAO) recommendation. The staff has now developed the first complete version of the RIRIP (Attachment 1). The plan contains (1) a statement of objectives and their relevance to the PRA policy statement and the agency's strategic plan; (2) a set of criteria and a process for deciding what to risk-inform; (3) guidelines for risk-informed activities; (4) a summary of activities planned to implement the risk-informed regulatory strategies that are described in the agency's strategic plan; (5) a description of an internal communications plan for soliciting and considering staff input and feedback on the agency's plan and progress toward implementing risk-informed regulatory initiatives; (6) a description of a training program to ensure that the staff has the knowledge and skills needed to implement risk-informed regulations; and (7) success measures.

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In a staff requirements memorandum (SRM) dated April 18, 2000, the staff was directed to include in the plan as complete a description as possible of an internal communications plan and staff training requirements. These descriptions are given in Part 3 of the RIRIP. The staff was also directed to identify internal and external factors that may hinder the planning process (discussed below).

## DISCUSSION

### RIRIP Purpose and Structure

The Commission's 1995 PRA policy statement provides guidance on risk-informing its regulatory activities. The Commission stated its vision that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." The RIRIP describes the staff's plans to achieve that vision by applying criteria to select regulatory requirements and practices, risk-informing those requirements and practices, and developing the necessary data, methods, guidance, and training. Thus, the RIRIP integrates the agency's risk-informing activities. This plan is also intended to explain the agency's activities, philosophy, and approach to risk-informed regulatory policy to internal and external stakeholders. The challenge in developing the RIRIP was to specify staff activities that are both necessary and sufficient to implement the strategies described in the NRC's strategic plan.

Part 1 of the plan explains the PRA Policy Statement and its relevance to the NRC's strategic plan. Part 1 also gives draft guidance on selecting "candidate" requirements, practices, and processes to risk-inform and on easing the transition to risk-informed regulation, summarizes the communication plan and training plan, and mentions the staff's efforts during calendar year 2000 to identify risk-informed regulatory milestones to be included in the performance plan.

Part 2 of the plan gives detailed information on the staff's transition activities for risk-informed regulation, including initiatives undertaken since the 1995 PRA policy statement. The activities are described as implementing the strategic plan strategies, with chapters addressing the Nuclear Reactor Safety Arena, the Nuclear Materials Safety Arena, and the Nuclear Waste Safety Arena. Each chapter is organized around the strategic plan strategies that are relevant to risk-informed regulation in that arena. The implementation activities for each strategy are described, and significant milestones are set for each activity. Attachment 2 lists significant accomplishments since SECY-00-0062 in March 2000.

Part 3 of the plan describes the training program for risk-informed regulation and plans for communicating the RIRIP.

### Important Factors for Risk-Informed Regulation

Since risk information will be used to complement the traditional deterministic approach, risk-informed activities should preserve certain key features of the deterministic approach in establishing risk-informed regulatory programs. Among these features are the fundamental safety principles of adequate protection, defense-in-depth, safety margins, value-impact, "as low as reasonably achievable" (ALARA) radiation protection, and the agency's safety goals. In risk-informing its requirements and practices, the staff should consider these principles to

ensure that regulations focus on the most important items and account for uncertainties affecting regulatory decisions. The RIRIP discusses each of these features.

#### Internal and External Impediments

As directed by the Commission in the April 18, 2000, SRM, the staff has continued to identify and resolve impediments to risk-informed regulation. In SECY-00-0162, the staff described its approach for addressing the issue of PRA quality in current risk-informed activities. In addition to PRA quality, public availability of risk information needs to be established to ensure all stakeholders have access to information used in safety decisions. Another important aspect of risk-informed regulation is the issue of voluntary versus mandatory implementation and the related issue of selective implementation of risk-informed requirements. The staff discussed both issues in SECY-00-0198 and SECY-00-0194. The staff intends to address both issues on a case-by-case basis. The staff discussed the issue of pilot plant participation in risk-informed regulation in the Nuclear Reactor Safety Arena in SECY-00-0194.

The staff recognizes the variable acceptance among the NRC staff and other stakeholders of the increased use of risk information in the regulatory process. This cautiousness poses a challenge for the staff as the activities discussed in the plan are undertaken and is a major reason for establishing communication and training initiatives to facilitate the transition to risk-informed regulation.

#### Future Activities

The staff will develop a strategy to solicit and consider staff input and feedback on the agency's plans for, and progress in, risk-informed regulation. Part 3 of the RIRIP describes a plan for communicating the RIRIP. Near-term milestones for communicating the RIRIP include a briefing of the ACRS/ACNW and solicitation of internal and external input on the RIRIP, possibly including one or more workshops. Since training is vital to facilitate the transition to risk-informed regulation, the agency will continue its efforts to increase the staff's knowledge of and skills in risk assessment and statistics. Part 3 of the RIRIP describes the agency's training program to support implementation of risk-informed regulation. Both training and communication activities will encourage a risk-informed culture and mind set among the staff.

During the coming months, the staff will continue to apply and refine the screening criteria for selecting candidate risk-informed requirements, practices, and processes. The results will be incorporated in the agency's planning, budgeting, and performance management (PBPM) process. The staff will develop criteria for selecting implementation activities to use as success measures in the performance plan the agency prepares for Congress.

#### COORDINATION

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

RESOURCES

The implementation activities described in this plan were prioritized through the PBPM process and the resources have been budgeted by each office consistent with their operating plans.

**/RA/**

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## Attachments:

1. Risk-Informed Regulation Implementation Plan
2. Significant Accomplishments in Risk-Informed Regulation

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## **Risk-Informed Regulation: Significant Accomplishments Since March 2000**

### Nuclear Reactor Safety Arena

- The revised reactor oversight process (described in SECYs-99-007, 99- 007A, and 00-0049) was implemented nationwide in April 2000. The staff has convened a task group to assess inspector training and qualifications in light of the new reactor oversight program and other risk-informed initiatives. The task group consists of representatives from NRR, HR, and the regions. The task group began meeting in July and August 2000 to plan its review.
- During a briefing on March 31, 2000, the Commission raised concerns regarding PRA quality and efforts required to work with standards development organizations such as the American Society of Mechanical Engineers, the American Nuclear Society, and the National Fire Protection Association. In SECY-00-0162, "Addressing PRA Quality in Risk-Informed Activities," dated July 28, 2000, the staff identified its approach for the scope of the PRA and technical attributes necessary to give an appropriate level of confidence in the results used in regulatory decision-making. The staff continues to actively participate in the standards development process to reach consensus on PRA quality requirements.
- The staff has completed its reviews and issued Staff Evaluation Reports (SERs) on Individual Plant Examination of External Events (IPEEE) submittals for 47 out of 70 operating reactor sites, including 16 since March 2000. The staff concluded that all of these 47 submittals met the intent of Supplement 4 to Generic Letter 88-20. The operating plan schedule to complete the review of all IPEEE submittals and issue plant-specific SERs by January 2001 is based on the assumption that licensees provide responses to requests for additional information (RAIs) by October 2000. The staff is still awaiting responses to RAIs from six plants (Byron, Braidwood, Calvert Cliffs, Perry, River Bend, and Sequoyah). The staff anticipates that almost all of the IPEEE reviews will be completed in accordance with the operating plan schedule. However, RAI responses for four plants are not expected until December 2000 to the first quarter of 2001. Therefore, the reviews for these plants will not be completed by January 2001 (the operating plan schedule). The operating plan calls for the staff to complete the draft IPEEE insights report six months after completing the draft report (i.e., October 2001). Although the staff is working on the draft IPEEE insights report in parallel with completing the plant IPEEE reviews, the schedule for the draft insights report may slip. The Commission will be informed if there is any change to these schedules.
- In April 2000, the Commission published an advance notice of proposed rulemaking (ANPR) inviting comments, advice, and recommendations from interested parties on the contemplated approach for a rulemaking that would modify the special treatment requirements set forth in Commission regulations. This project is commonly known as Risk-Informed Part 50, Option 2. In SECY-00-194, "Risk-Informing Special Treatment Requirements," dated September 7, 2000, the staff provided preliminary views on the comments received on the ANPR and presented an approach for rulemaking.

- The staff made progress on its study of possible risk-informed changes to the technical requirements of 10 CFR Part 50. This project is commonly known as Risk-Informed Part 50, Option 3. On April 12, 2000, the staff provided its first status report in SECY-00-0086, "Status Report on Risk-Informing the Technical Requirements of 10 CFR Part 50 (Option 3)" and also indicated its intention to expedite recommendations for risk-informed changes to 10 CFR 50.44, "Standards for Combustible Gas Control System in Light-Water-Cooled Power Reactors." On September 14, 2000, the staff provided the second status report on these activities 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." This paper provided recommendations for risk-informed changes to 10 CFR 50.44. In addition, the staff has been meeting with stakeholders (both external and internal) to obtain their input on these activities, and initiating work to develop risk-informed alternatives to 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors."
- The staff recommended and the Commission approved developing additional guidance on a risk-informed approach to decide whether undue risk exists when all other regulatory requirements appear to be satisfied. The staff forwarded proposed guidance to the Commission on October 12, 1999, in SECY-99-246, "Proposed Guidelines for Applying Risk-informed Decisionmaking in License Amendment Reviews." The Commission approved the approach in license reviews as well as implementation of the process on an interim basis while the staff modified related guidance documents and engaged stakeholders. The staff disseminated the interim guidance to the industry via Regulatory Issue Summary (RIS) 2000-7 on March 28, 2000. The staff plans to formally issue the guidance via modification of Regulatory Guide 1.174 and by writing a new appendix to Chapter 19 of the Standard Review Plan.<sup>1</sup> On April 10, 2000, the proposed appendix was published for public comment and a public meeting was held on May 16, 2000, to discuss it. The proposed appendix has been discussed with the ACRS and CRGR and the staff recently forwarded it to the Commission for approval.

#### Nuclear Materials Safety Arena

- Work is ongoing to systematically perform a risk analysis of byproduct materials to incorporate risk insights into NMSS regulatory activities, as discussed in SECY-99-100. In SECY-00-0048, "Nuclear Byproduct Material Risk Review," the staff transmitted, to the Commission, NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," and the staff's approach for use of the technical information. The staff's review of the analysis did not find any areas of regulation or policy needing immediate revision, to address a safety issue. The staff, with contractor support, is conducting an uncertainty analysis of some of the data. However, the staff has used, and will continue to use, the insights gained through the analysis, and will incorporate additional information as it becomes available. In addition

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<sup>1</sup>An update to RG 1.174 and SRP Chapter 19 to reflect this and other new information will be published for public comment in FY2001.

to incorporating insights into NMSS risk efforts, the staff plans to use results documented in NUREG/CR-6642 to support the performance goals of the “Planning, Budgeting, and Performance Management” process, and to use the report and its supporting database as resources for evaluating risk issues in byproduct material activities:

- SECY-00-0001 and the associated Staff Requirements Memorandum (SRM) were issued on the staff’s proposed medical pilot program (nuclear medicine program) to streamline inspection and enforcement of materials licensees. The approach will assess a licensee’s performance relative to desired outcomes. A risk-informed, performance-based Temporary Instruction for the medical pilot program will use a focus-element approach to assess a licensee’s performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections.
- The staff continued its progress on materials guidance consolidation, including the integration of risk information, with the final publication of the following volumes of NUREG-1556, “Consolidated Guidance about Materials Licensees”:

Vol. 6	“Program-Specific Guidance about 10 CFR Part 36 Irradiators”
Vol. 7	“Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope”
Vol. 11	“Program-Specific Guidance about Licenses of Broad Scope”
Vol. 13	“Program-Specific Guidance about Commercial Radiopharmacy Licenses”
Vol. 14	“Program-Specific Guidance about Well-Logging, Tracer, and Field Flood Study Licenses”

Future revisions will use the insights and information contained in NUREG/CR-6642, “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems.”

- The staff has developed the final rulemaking package for the revision of 10 CFR Part 35, in accordance with the SRM on SECY-99-201, dated February 16, 2000. The final rulemaking package and the associated guidance document are currently under Commission review; the revised Medical Policy Statement was published in the *Federal Register* on August 3, 2000. The SRM noted that the rule is risk-informed and significantly reduces the regulatory burden in many areas.
- In light of the recent overexposures at Mallinckrodt facilities in Regions I and III, a working group has been established to review the findings of the inspections, and to develop lessons learned for radiopharmaceutical facilities, which will incorporate risk insights. As part of a broader, second-phase activity, a second working group will be established to review the overall materials program and to recommend necessary changes to areas such as regulations, the licensing and inspection program, and the current enforcement policy.

- On June 23, 2000, SECY-00-0137 was sent to the Commission to inform the Commission of the staff's decision to deny Seaman Nuclear Corporation's request to distribute the C-300 portable moisture density gauge to general licensees. Gauges of this type are currently distributed to specific licensees only. Risk insights from NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," along with the regulations of 10 CFR 32.51, were used to determine the level of risk posed by the gauge to general licensees, and to the public.
- In response to the Commission's SRM for SECY-99-100, the staff has produced a plan of action for developing materials safety goals and screening criteria for applying risk analysis. The plan was developed through enhanced participation by the public in two meetings. The first step is to conduct studies of specific regulatory cases in the materials and waste arenas to illuminate implicit safety criteria and the potential benefits of risk information. These case studies will be conducted during FY 2001.
- A program has been initiated to train Headquarters and Regional technical staff, working in the materials and waste arenas, in methods of risk analysis appropriate to regulation in these arenas. A pilot training course was held September 11-14, 2000. Feedback from the pilot class will be used to create a final version of the class, which will be implemented in December 2000.
- On September 18, 2000, the Commission published the final rule revising 10 CFR Part 70 to require that Integrated Safety Analyses (ISAs) be performed by major fuel cycle licensees. This concludes a 7-year rulemaking effort, with heavy involvement from stakeholders, to regulate fuel cycle facilities in a more objective risk-informed, performance-based manner. These ISAs will identify both nuclear and chemical accidents, estimate their consequences, and evaluate the controls limiting their likelihoods.
- NMSS has established the foundation and framework for making the fuel cycle oversight program more risk-informed and performance-based. Since beginning the initiative in May 1999, the U.S. Nuclear Regulatory Commission (NRC) conducted seven public workshops with stakeholders to develop the framework and foundation for the revised oversight program, including cornerstones of safety and safeguards. In the most recent meeting with stakeholders in September 2000, stakeholders met with NRC and identified priority revisions for development, along with the sequence for completing the revisions. The revised oversight program will include risk-informed inspections, risk-significance determination, more scrutable and predictable enforcement and assessment of licensee performance, and enhanced communications with stakeholders. The revised oversight program will build on the risk-informed regulations associated with the new Part 70 rulemaking, and will focus on the results of licensees' ISAs. The staff plans to inform the Commission of the status of the revised oversight program in a paper and briefing in December 2000.



Nuclear Waste Safety Arena

- In FY 2000 the staff completed the final Yucca Mountain site-specific rulemaking package, 10 CFR Part 63. Revision 1 of the Yucca Mountain Review Plan was also completed. This revision includes guidance on programmatic requirements and on evaluating both pre- and post-closure safety assessments. This version was specifically revised, to assure that both its contents, and the reviews conducted using it, are risk-informed, so as to focus the proper level of effort in areas important to the findings.
- NRC staff has completed the update of the "Sufficiency Review Strategy." This strategy will be used to guide the staff's development of preliminary comments on the sufficiency of the U.S. Department of Energy's (DOE's) at-depth site characterization analysis and waste form proposal, for inclusion in a license application. The strategy directs the staff to focus the sufficiency review on the areas that are most important to DOE's estimates of repository performance. The strategy identifies several factors to be considered in emphasizing specific areas in the review, including contribution to risk, importance to the DOE "licensing" case, DOE's treatment of uncertainty, and the degree of conservatism used in the DOE analyses. The Yucca Mountain Review Plan will be used to focus the sufficiency review. Staff guidance is currently being developed to implement the strategy.
- In September 2000, staff finalized the NMSS Decommissioning Standard Review Plan (SRP). The SRP will guide staff's review of decommissioning plans submitted by licensees in accordance with the final license termination rule (10 CFR Part 20, Subpart E). As directed by the Commission, the SRP incorporates a risk-informed, iterative approach that will allow NRC staff to evaluate information submitted by licensees in a timely, efficient, consistent manner, and ensure the protection of public health and safety.
- A pilot probabilistic risk analysis (PRA) of a spent fuel dry cask storage system is being performed for the NMSS Spent Fuel Project Office (SFPO) by the Office of Research (RES) to assess the potential risk to the public from the storage of spent nuclear fuel from a civilian nuclear reactor. This project will develop a method for performing a probabilistic risk assessment, for spent fuel dry cask storage systems, that will lead to recommendations as to whether it would be cost beneficial for PRAs to be performed for every cask design and site. This pilot will be performed using the Holtec International HI-STORM 100 system. In FY 2000, RES prepared a list of potential initiating events to be used in four event tree models for mechanical, thermal, criticality and other type accidents. RES also prepared a supporting list of more detailed event and action scenarios to be used in the future task of assigning probabilities to the different event tree branches. A final report on screening/preliminary consequence analysis is scheduled for October 2001.
- In FY 2000, NRC published NUREG/CR-6672, "Reexamination of Spent Fuel Shipment Risk Estimates." The report, prepared by Sandia National Laboratories under contract

to SFPO, provides an updated assessment of generic spent fuel transportation risks for possible future shipments to centralized storage facilities and/or a repository. NUREG/CR-6672 employs a best-estimate approach, and includes both incident-free and accident dose risks. For the shipment accident analyses, risk results are presented in terms of the probability of exceeding a given consequence (collective dose). Based on the findings of NUREG/CR-6672, the staff finds no technical basis to reopen or supplement NRC's transportation environmental impact statement (NUREG-0170, "Final Environmental Statement on the Transportation of Radioactive Materials by Air and Other Modes").

- A "Package Performance Study" is under way that will focus on spent nuclear fuel cask responses to severe transportation accidents. Several public meetings have been held using a public-participation approach to solicit stakeholder interest. A World Wide Web site has been established to facilitate interactions on the project. Ongoing public interactions throughout this project will help ensure that public concerns are effectively identified and understood. The first product study will be an "Issues and Resolutions Option Report," scheduled for mid-2000.
- On June 28, 2000, the staff provided the Commission with SECY-00-0145, which presented an integrated rulemaking plan for decommissioning in the areas of emergency planning; insurance; safeguards; staffing & training; and backfit. The rulemaking plan is based on risk information to the extent provided by the staff's technical risk study. However, the rulemaking plan also has prescriptive requirements that lead to regulatory clarity and confidence that are not strictly risk-informed. The staff is finalizing the technical study on spent fuel pool accident risk at nuclear power plants undergoing decommissioning. This report will provide the technical basis for many of the proposed regulatory improvements.