

## INFORMATION PAPER

SECY-00-0062

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FOR: The Commissioners  
FROM: William D. Travers /RA/ Executive Director for Operations  
SUBJECT: RISK-INFORMED REGULATION IMPLEMENTATION PLAN

- **PURPOSE:**
- **BACKGROUND:**
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  - Significant Accomplishments
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### **PURPOSE:**

To provide the Commission with (1) a summary of significant accomplishments in risk-informing regulatory processes and practices since the August 1999 update of the PRA Implementation Plan ([SECY 99-211](#)), (2) an initial, albeit incomplete, example of the form, content, and structure of the revised (and renamed) PRA Implementation Plan and, (3) a description of issues that have affected or may affect the implementation of the Commission's risk-informed activities.

### **BACKGROUND:**

For the past several years, the agency's work to expand the use of PRA has been tracked in the PRA Implementation Plan (PRA-IP). Quarterly updates of the plan were provided to the Commission to summarize ongoing work, key accomplishments, and significant changes in the plan.

In SECY-99-211, the most recent update of the PRA-IP, the staff advised the Commission that, to meet agency commitments set forth in its response to the March 1999 GAO report, they would restructure the PRA Implementation Plan to more clearly describe our risk-informed activities, provide linkage of these activities to the agency's Strategic Plan, and change the frequency of updating from quarterly to semi-annually.

In a January 13, 2000, memorandum to the Commission, the staff provided a proposed outline of that revised report and noted that the title would be changed from the "PRA Implementation Plan" to the "Risk-Informed Regulation Implementation Plan" (RIRIP). This name change was proposed to better characterize the nature and purpose of the plan.

That memorandum noted further that the RIRIP would:

1. Be organized to track three principal arenas in the Agency's Strategic Plan (Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety),
2. Provide clear objectives and linkages to the PRA Policy Statement and to the Agency's Strategic Plan,
3. Identify criteria for the selection and prioritization of practices and policies to be risk-informed and guidelines for implementation,
4. Identify major pieces of work associated with these efforts and related major milestones, including plans for communicating information to stakeholders.

An initial version of the RIRIP is attached, and described in more detail below. Development of a final version awaits other ongoing staff work, including completion of the Strategic Plan and work in NMSS to develop plans for risk-informing their activities.

### **DISCUSSION:**

#### **Significant Accomplishments**

[Attachment 1](#)  lists significant staff accomplishments in implementing the Commission's PRA Policy Statement and related guidance since the August 1999 PRA-IP update. The most significant accomplishments for each Strategic Arena include:

##### *Nuclear Reactor Safety Arena*

- In response to Commission guidance on risk-informing its regulations and related guidance on nuclear power plant

design and operation, the staff proposed (in [SECY-99-256](#)) a detailed rulemaking plan that would modify the special treatment requirements set forth in Commission regulations. This item is referred to as Option 2 in the effort to risk-inform [10 CFR Part 50](#). The voluntary alternate approach would vary treatment of systems, structures, and components (SSCs) on the basis of their safety significance using a risk-informed categorization method. The staff recommended the Commission approve the publication of an Advance Notice of Proposed Rulemaking (ANPR) setting forth the details of the staff's proposal for public comment. The Commission recently approved this plan with comments. The ANPR was published in the Federal Register in March 2000.

- A plan for re-examining the technical requirements set forth in 10 CFR Part 50 and related guidance documents was prepared for Commission consideration ([SECY-99-264](#)). This item is referred to as Option 3 in the effort to risk-inform 10 CFR Part 50. This plan proposes to incorporate risk insights into the regulatory process through a systematic examination of current requirements, identification of requirements that warrant modification, and development of specific recommendations for Commission approval. The Commission recently approved this plan with comments. A public workshop was held on February 24 and 25, 2000, to present initial results of staff work and to solicit stakeholder comment.
- A nine-plant pilot program to demonstrate the feasibility of the revised reactor oversight program ([SECY-99-007, 007A](#)) was successfully completed and a summary report provided to the Commission in [SECY-00-0049](#).
- 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 in October 1999 ([SECY-99-246](#)). The Commission approved the approach in license reviews as well as implementation of the process on an interim basis while the staff modifies related guidance documents and engages stakeholders. The staff's proposed schedule was forwarded to the Commission in February 2000. Final documents are expected to be forwarded to the Commission in September 2000 following review by ACRS and CRGR.
- The industry completed implementation of their accident management (A/M) programs in December 1999. Key elements of A/M include implementing plant-specific severe accident management guidelines, incorporating severe accident information into licensee training programs, and conducting periodic A/M drills. NRC is exploring ways to maintain oversight of utility A/M capabilities within the context of the risk-informed reactor oversight process.
- In February 2000, the staff submitted a draft technical study to the Commission on spent fuel pool (SFP) accident risk at decommissioned nuclear power plants. The technical study provides an interim, risk-informed technical basis for reviewing exemption requests, and it provides a regulatory framework for integrated rulemaking. The staff developed the report in response to a Commission request to consider whether the risk from decommissioning plants was low enough to justify generic regulatory relief in the areas of emergency planning, insurance indemnification, and safeguards.
- The staff issued Draft Regulatory Guide [DG-1082](#) for public comment in December 1999 that proposes to endorse an industry document, [NUMARC 93-01](#), "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." Because of dialogue with stakeholders, the final version of the Nuclear Energy Institute (NEI) document is expected to meet the staff's needs.
- The American Nuclear Society has begun work to develop a consensus PRA standard covering reactor accidents that are initiated during low power and shutdown conditions. This standard will incorporate into PRAs the effects of accidents initiated by internal fires and external events. The staff is supporting this effort.
- Since July 1999, 33 risk-informed licensing actions have been approved.

#### *Nuclear Materials Safety Arena*

- Work has been completed on the Risk Analysis of Byproduct Materials project that will be used to incorporate risk insights into NMSS regulatory activities as discussed in [SECY-99-100](#). The NMSS staff has prepared a Commission paper transmitting the final report (NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems") to the Commission. The staff's review of the study did not find any areas of regulation or policy in need of immediate revision to address a safety issue. In addition to incorporating insights into NMSS risk efforts, the staff plans to use results of the NUREG/CR report to support the performance goals of the Planning, Budgeting, and Performance Management process and to use the NUREG/CR report and its supporting database as a resource for evaluating risk issues in byproduct material activities.
- The NMSS staff has completed its reexamination of NUREG-0170, "Transportation of Radioactive Material by Air and Other Modes." NUREG-0170, which was issued in 1977, provided the regulatory basis for the issuance of general licenses for transportation of radioactive material. The reexamination addressed the increase in spent fuel shipments expected over the next few decades, as well as shipments to facilities along routes and in casks not specifically examined by NUREG-0170. The report documenting this reexamination will be published at the end of March 2000.
- [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 licensee's performance relative to desired outcomes. A risk-informed, performance-based Temporary Instruction (TI) for the medical pilot program will use a focus element approach to assess licensee performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections.


- The Commission has approved the staff's proposal contained in [SECY-99-201](#), which included the proposed revision of [10 CFR Part 35](#), "Medical Use of Byproduct Material." The revised rule focuses NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and establishes a risk-informed and more performance-based regulatory structure consistent with the NRC's Strategic Plan. The staff used a risk-informed approach to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health. Risk information that was considered during the development of the rule included events in NRC's Nuclear Materials Event Database, the external review and report by the National Academy of Sciences-Institute of Medicine, a 1993 NRC internal management review and report, the Commission's Strategic Assessment and Rebaselining Project, and comments provided by the stakeholders and the public.

#### *Nuclear Waste Safety Arena*

- The staff has completed, and will provide to the Commission in March 2000, the final Yucca Mountain site-specific rulemaking package (10 CFR Part 63). Revision 0 of the Yucca Mountain Review Plan (the Postclosure Safety Evaluation Chapter only) will accompany the rulemaking package. Revision 1 of the plan (which will include a preclosure safety evaluation, as well as administrative and programmatic requirements) is scheduled to be completed by September 2000.
- On February 17, 2000, the staff sent SECY-00-0042 to the Commission. The paper informs the Commission of the roles of past and present spent nuclear fuel transportation risk studies. The staff has already completed two transportation risk studies; a third is presently nearing completion; and a fourth was recently initiated. SECY-00-0042 discusses NRC's continuing efforts in conducting spent fuel transportation risk studies, the contribution of each to the Commission's transportation safety program, and plans for future communication with the public on spent fuel transport risk.


### **Risk-Informed Regulation Implementation Plan Structure and Content**

Since the January 13, 2000, memorandum to the Commission, the staff has been working to develop the RIRIP to more effectively communicate the full extent of, as well as the integration of, the Commission's efforts to risk-inform its processes. The RIRIP includes guidelines for identifying, prioritizing, and implementing risk-informed changes to regulatory processes.

[Attachment 2](#)  provides a connection among agency strategies, activities, programs, and program milestones. It also provides a structure for describing the related "infrastructure" needs, i.e., methods, guidance, staff training, and communication needed to fully implement the program. However, it is limited to describing example information on certain activities in the Nuclear Reactor Safety Arena. The staff believes that this example provides the Commission with a sufficiently broad view of the general scope and direction of the revised RIRIP to permit its evaluation as a tool and roadmap for communicating Commission plans for risk-informing its processes and procedures.

The staff has begun implementing the process for risk informing NMSS activities described in SECY 99-100. The Commission, in approving SECY 99-100, endorsed the staff's plans to implement a process for identifying candidate applications, making decisions on how to modify those applications, implementing new risk informed approaches, and developing or adapting tools and techniques of risk analyses to the waste and materials activities. In addition, the Commission directed the staff to develop appropriate materials safety goals, analogous to the reactor safety goal. Strategies for meeting the Performance Goals included in the Nuclear Materials Safety and Nuclear Waste Safety Chapters of the Draft Strategic Plan reflect our commitment to this effort and its importance in meeting our goals. The staff is currently in the process of defining and developing the specific work activities that are necessary and sufficient to accomplish the strategies.

In parallel with defining more the detailed work activities discussed above, a number of short term activities for risk informing NMSS have begun, including the following: (1) ensuring current activities within the Waste and Materials Strategic Arenas that are being risk-informed are being done so in an appropriate manner; (2) defining the criteria for identifying those areas and activities that are likely to be improved by being risk-informed, identifying the areas and activities that fit the criteria and prioritizing any new risk informed activities; (3) identifying those areas where developing and articulating a qualitative safety goal would add value (e.g., contribute to a Performance Goal); and, (4) developing and implementing a program for both general and specific staff training on risk assessment and risk management in the Waste and Materials Areas.

In the next update to the Plan outlined in [Attachment 2](#)  the staff intends to include and integrate the Nuclear Materials Safety and Nuclear Waste Safety activities.

It is important to note that an integrated communication plan to support the Commission's risk-informing activities is a key element of the RIRIP that remains to be fully developed. NRC staff awareness of the scope, direction, and progress of current risk-informing initiatives is critical to the success of using a risk-informed approach to revising regulatory processes and practices. Training, meetings, and workshops, as well as the "message mapping" approach recently presented to the staff, are all methods that will be considered. Implementation of this communication plan will become an integral element in the revised RIRIP. Communication with external stakeholders is equally important. Communication with these stakeholders will be integrated into work plans for specific risk-informed activities and will be described in the RIRIP.

## Key Issues

The following issues and staff actions are highlighted for the Commission since they have affected or could adversely affect the staff's plans and schedules for executing its risk-informed activities.

### *IPE/IPEEE Followup*

In SECY-98-012, the staff described its program to review Individual Plant Examination (IPE) program results to determine if:

- any additional plant-specific improvements are warranted
- licensees have followed through on the actions they indicated they were taking as a result of their IPE and
- any additional generic regulatory activities should be undertaken.

SECY-98-012 described a series of activities to address these three issues. After the program had been started, other activities were initiated that were related to and could impact the plans for the IPE follow-up. These activities included the risk-informed modifications to 10 CFR Part 50 as described in SECYs-98-300, 99-256, and 99-264. In the August 1999 PRA-IP update, it was noted that the staff was currently working with industry groups to develop IPE follow-up activities that are complementary with the risk-informed Part 50 process. Accordingly, plans for IPE followup have been modified as described below.

Since the IPEs have been completed, many licensees continue to update and improve their PRAs and related insights. During 1999 and 2000, the staff has met with NEI, nuclear steam supply system (NSSS) owners groups, licensees, and members of the public to explore ways to facilitate a regular voluntary exchange of current risk-related information useful in addressing plant-specific, owners-group-specific, and generic issues of a risk-informed regulatory nature. Currently, the various stakeholders are considering an ongoing cooperation with respect to the following initiatives:

- Annual reporting of progressive PRA insights and plant improvements that reduce risk.
- Ensuring that NRC risk-informed assessment tools and processes use the most current information.
- Providing a forum to address generic and owners-group-specific technical issues that arise from the reactor oversight process or other NRC reviews.
- Identifying generic risk insights that can be applied in the resolution of issues associated with severe accident mitigation alternatives.

The staff will continue to work with stakeholders in this area.

### *PRA Standards*

As noted in previous Implementation Plan updates and the Chairman's Tasking Memorandum (CTM), the staff has been encouraging and participating in the development of consensus PRA standards by the American Society of Mechanical Engineers (ASME), American Nuclear Society (ANS), and the National Fire Protection Association (NFPA). The staff's goals with respect to these standards are to improve the quality and consistency of PRAs and reduce the required review effort by the staff when PRA information is used in regulatory activities. A key example of this is provided in SECY-99-256, (Option 2 in risk-inform Part 50) in which the proposed Advanced Notice of Proposed Rulemaking indicates that PRAs used to support the SSC categorization process should conform to the consensus ASME/ANS PRA Standard documents, as endorsed by the NRC. This will support the possibility of an approach where no prior application-specific NRC review and approval will be required of the PRA.

As indicated in the CTM, the ASME standards development work has been the subject of concern by the staff with respect to the timing of its completion and the adequacy of its technical content. It is now clear that completion of the standard will be delayed, to the point that it may not be available by publication of the proposed special treatment rule. The staff is continuing to urge ASME to complete the standard in a timely manner, continuing to provide staff resources to help draft the standard, considering alternative language for use in the proposed rule, and developing plans for expediting the review and, if appropriate, endorsement of the standard when it is completed.

### *Review of Inservice Inspection Topical Reports*

On June 11, 1998, the staff sent to the Commission SECY-98-139, which transmitted Regulatory Guide 1.178 and Standard Review Plan (SRP) Section 3.9.8 for trial use. These documents provide guidance to licensees and staff regarding risk-informed inservice inspection (RI-ISI) programs for piping systems. As stated in SECY-98-139, the staff issued the documents for trial use for the following reasons:

- The documents did not have the benefit of insights gained from pilot plant applications during development. The Commission Paper stated that the pilots were expected to be completed by the end of December 1998.
- The industry had submitted topical reports with two different methods, one developed by Westinghouse Owners Group

and the other by Electric Power Research Institute (EPRI), for incorporating risk insights into their RI-ISI programs. The Commission Paper stated that the staff's review of the topical reports was expected to be completed by the end of December 1998.

- The staff was reviewing three ASME Code Cases (N-560, N-577, and N-578) in parallel with the pilot plant submittals.

In SECY-98-139, the staff stated that upon completion of the review of the industry topical report and the three pilot plant reviews, the staff would incorporate lessons learned from those reviews into Regulatory Guide 1.178 and the SRP and issue them as final documents. It was expected that this would take approximately 12-18 months from the June 11, 1998, paper including time for ACRS and CRGR reviews.

Since the issuance of SECY-98-139, the staff has completed reviews of RI-ISI programs from four pilot plants and approved the methodologies presented in the two industry topical reports. However, industry schedules for RI-ISI submittals slipped such that the pilot plant reviews could not be completed until August 1999. The industry submittal for one of the methodologies (EPRI Report) was also delayed such that review and approval was delayed from the end of December 1998 to October 1999. The three ASME code cases are still being revised to incorporate lessons learned in the review and approval of the pilot plant submittals and industry methodologies.

As stated above, the staff has approved four risk-informed ISI submittals. Three more are currently under review. However, as expected, the pilot program and other reviews have identified areas where the industry wants to modify the original generic framework. The Westinghouse Owners Group has submitted an addendum to its RI-ISI topical report that proposes to incorporate augmented programs not covered by the methodology approved by the staff. Furthermore, both the Westinghouse Owners Group and EPRI are meeting with the staff to discuss the possibility of expanding the RI-ISI methodology to include augmented inspection programs such as high energy line break exclusion zone piping and components other than piping.

The staff believes that work to revise [Regulatory Guide 1.178](#) and the SRP should not commence until further experience is acquired with the revised industry methodologies (expected to be evaluated by the end of December 2000) and the finalization of the three ASME Code Cases (expected by June 2000). Contingent upon these completion dates, the staff expects to finalize Regulatory Guide 1.178 and the SRP by the end of December 2001 (18 months from the completion of the ASME code cases), including time for ACRS and CRGR reviews.

#### *Impediments to the Increased Use of Risk-Informed Regulation*


In its February 14, 2000, letter to Chairman Meserve, the ACRS described a number of technical impediments to the increased use of risk information in agency regulatory activities. These included:

- PRA inadequacies and incompleteness in some areas.
- The need to revisit risk-acceptance criteria.
- Lack of guidance on how to implement defense in depth and how to impose sufficiency limits.
- Lack of guidance on the significance of and appropriate use of importance measures.
- Variation of PRA quality and scope and the need for standards.

A number of staff activities are under way that will, at least in part, remove or reduce the impact of these impediments. The staff will continue to work with the ACRS to ensure that necessary activities to address the impediments are defined and summarized in the RIRIP.

## **RECOMMENDATIONS:**

The staff recommends the Commission:

- NOTE: The accomplishments in risk-informing Commission processes and practices as set forth in [Attachment 1](#) .
- NOTE : The delay in development of the ASME consensus PRA standard and its potential impact on implementing current risk-informed activities. The staff is continuing to urge ASME to complete the standard in a timely manner, continuing to provide staff resources to help draft the standard, considering alternative language for use in the proposed rule, and developing plans for expediting the review and, if appropriate, endorsement of the standard when it is completed.
- NOTE: The changes in staff plans for IPE follow-up activities and inservice inspection topical report reviews, and
- NOTE: That the staff will continue work to resolve the issue of duplicative tracking systems and to expand the RIRIP as additional plans are developed.

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[Attachments](#)



1. Significant Accomplishments-Risk-Informed Regulation
2. Risk-Informed Regulation Implementation Plan (Partial Draft)