

## INFORMATION PAPER

March 15, 2000

SECY-00-0062

FOR: The Commissioners

FROM: William D. Travers /RA/  
Executive Director for Operations

SUBJECT: RISK-INFORMED REGULATION IMPLEMENTATION PLAN

### 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.

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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 on-going 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.

- 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)

Distribution:

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SIGNIFICANT ACCOMPLISHMENTS  
RISK-INFORMED REGULATION

**NUCLEAR REACTOR SAFETY ARENA**

**LICENSING**

- (1) 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.
- (2) The staff performed the first annual assessment of needed changes to the risk-informed regulatory guides and Standard Review Plan sections. These assessments are described in memoranda to the Commission dated June 30, 1999, and August 30, 1999.
- (3) The staff has completed reviews and issued Staff Evaluation Reports on Individual Plant Examination - External Events (IPEEE) submissions from 29 out of 70 operating reactor sites, including six since July 1999, and provided an assessment of the risk impacts of current Appendix R exemptions in SECY 99-182.
- (4) 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.
- (5) 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 report was initiated by the Commission when they asked the staff 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.
- (6) The staff issued Draft Regulatory Guide DG-1082 for public comment in December 1999, which 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.

- (7) The staff is currently interfacing with Calvert Cliffs Nuclear Power Plant staff and with the Combustion Engineering Owners Group (CEOG) to identify the reasons behind the higher core damage frequency (CDF) of Calvert Cliffs than other CEOG plants. Once such reasons are identified, the licensee may consider appropriate changes in the PRA models and/or cost beneficial improvements in plant design and operation that would reduce the CDF. The licensee is scheduled to present its status and plans to the staff during a public meeting in April 2000.

## RULEMAKING

- (1) 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.
- (2) 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.
- (3) The staff identified the need to more fully assess the risks of accidents that might occur during operations at low power or during plant shutdown (LP/SD). A Commission paper was prepared (SECY-00-0007) that summarized the current state of knowledge regarding these accident risks. A plan was proposed that would identify and resolve issues associated with understanding the risk from these operations. That plan recommends continuation of the work with the American Nuclear Society (ANS) to develop a PRA standard explicitly directed at LP/SD operating states, the development of guidance (to staff and industry) for considering LP/SD risks in regulatory activities, as well as the development of related assessment tools.
- (4) The staff has been working with the National Fire Protection Association (NFPA) to develop an alternative performance-based, risk-informed fire protection standard for nuclear power plants. A draft standard has been issued for public comment and resolution of comments is expected by the end of CY 2000. A rulemaking plan was submitted to the Commission (SECY-00-0009) that would, after final Commission endorsement, provide for incorporation of that standard into Commission regulations as a voluntary alternative to current fire protection requirements.

- (5) Both the industry and the Commission staff have expressed interest in using PRA technology to deal with outstanding safety issues in the area of fire protection and to establish improved requirements for fire protection in nuclear power plants. To support this aspect of PRA use, the staff has developed a research plan that is aimed at closing those gaps in PRA technology that are needed to support improved, risk-informed fire protection requirements. That plan was developed in close consultation with industry, the ACRS, and national standards setting groups such as the NFPA.
- (6) The NRC has completed a new rule that allows operating reactor licensees the option of using an alternative source term for the analyses of design basis accidents. The new source term is based on more realistic fission product releases and timing. Its use in analyses is expected to result in reduced burden to both licensees and the Commission staff while at the same time ensuring safety is maintained. A draft regulatory guide has been issued for public comment.
- (7) The staff is continuing its support of the American Society of Mechanical Engineers (ASME) PRA standards development work. A draft consensus standard covering PRA Level 1 (full power operation, internal initiators) was developed and issued for public comment in May 1999. Extensive revisions to that draft are in progress. The schedule for completion of Phase 1 has been revised based on the large number of diverse comments received on the draft standard. Resolution of these comments by the ASME is progressing. However, the ASME effort is behind schedule with a current projected completion date of January 2001. Because some currently scheduled risk-informed activities are based on a PRA standard being in place by June 2000, 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 the alternative language for use in the ANPR, and developing plans for expediting the review and, if appropriate, endorsement of the standard when it is completed.
- (8) 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.

#### EVENT EVALUATION

- (1) The annual report on Accident Sequence Precursors was issued. That report reflects staff analyses of Licensee Event Reports, Augmented Inspection Team (AIT) reviews, and events identified from other sources. Seven system and two component reliability studies were also issued.

#### OVERSIGHT

- (1) 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.

- (2) Following a successful pilot demonstration program, additional worksheets have been prepared that will allow inspectors to implement the NRR's Significance Determination Process at all operating reactors.
- (3) A new fire protection baseline inspection program, which includes a new fire protection risk significance screening methodology, was piloted at three plants between November 1999 and January 2000. Revisions to this process based on lessons learned are being incorporated by the staff. Initial fire protection baseline inspections will commence at all plants in April 2000.

## **NUCLEAR MATERIALS SAFETY ARENA**

- (1) 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.
- (2) SECY-00-0001 and the associated 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.
- (3) 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.
- (4) The Division of Industrial and Medical Nuclear Safety continued its progress on guidance consolidation, including the integration of risk-information, with the final

publication of the following NUREG-1556, "Consolidated Guidance about Materials Licensees," volumes:

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

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."

- (5) Additional progress has been made in developing a risk-informed, performance-based proposed revision to 10 CFR Part 70 in an effort to improve the safety at fuel cycle facilities, while optimizing the burden. The Commission approved the proposed revisions and issued a proposed rule for comment in July 1999, which culminated a substantial staff effort and outreach program that included extensive coordination with interested stakeholders. The proposed change to the regulation requires a systematic and integrated review of potential accidents while allowing flexibility in specific preventive and mitigative measures. The staff continues to work with industry and other stakeholders to resolve comments concerning the associated Standard Review Plan (SRP). The staff intends to provide a final rule and associated Standard Review Plan to the Commission in May 2000.
- (6) The staff is developing the final rulemaking package for the revision of Part 35, in accordance with the staff requirements memorandum (SRM) on SECY-99-201, dated February 16, 2000. The Commission approved the rule language and directed the staff to complete the final Part 35 rulemaking package, the associated guidance document, and the revised Medical Policy Statement. The SRM noted that the rule is risk-informed and significantly reduces the regulatory burden in many areas.
- (7) The staff has initiated a revision of the fuel cycle safety inspection program to optimize the regulatory burden while ensuring safe operations. The staff's initiative is further described in SECY-99-188, "Evaluation and Proposed Revision of the Nuclear Fuel Cycle Facility Safety Inspection Program," that was issued in July 1999. A task force was established to develop performance indicators and identify risk insights to assess facility performance. Several public stakeholder meetings have been held including one on February 22-23, 2000.
- (8) In response to the Commission's SRM associated with SECY-99-100, the staff has initiated several actions that include planning a Public Workshop on development of criteria for prioritizing of NMSS risk-relevant activities, to be held on April 25, 2000, and working with the Office of Human Resources (Technical Training Center) to develop a class to train NMSS staff on risk assessment techniques. The pilot presentation of this class is planned for July 2000.

- (9) In cooperation with RES, NMSS has initiated a spent fuel dry storage cask PRA. Risk insights from the study will be used to support the staff's decision-making activities involving dry cask storage. Milestones for completion are in the process of being developed.
- (10) The 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. In 1996, the NRC decided to reexamine the risks associated with the shipment of spent reactor fuel by truck and rail. The reexamination was initiated (1) because many spent fuel shipments are expected during the next few decades, (2) because these shipments will be to facilities along routes and in casks not specifically examined by NUREG-0170, and (3) because the risks associated with these shipments can be estimated using new data and improved methods of analysis. If approved, the entire report documenting the reexamination will be published at the end of March 2000.
- (11) In response to an NMSS user need, RES staff completed an analysis on the risk associated with fixed nuclear gauges. The study focused on facilities that use nuclear gauges and on steel mills where gauges might be melted and cause an environmental release of radioactive material. The study (NUREG-1669), which is being prepared for publication, should be useful to both the regulators in implementing risk-informed regulations and stakeholders interested in reducing the risk associated with the use of nuclear gauges.
- (12) 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.

#### **NUCLEAR WASTE SAFETY ARENA**

- (1) The staff has completed, and will provide the final Yucca Mountain site-specific rulemaking package (10 CFR Part 63) to the Commission in March 2000. Revision 0 of the Yucca Mountain Review Plan (Postclosure Safety Evaluation Chapter only) will accompany the rulemaking package. Revision 1 of the Yucca Mountain Review Plan (which will include a preclosure safety evaluation and administrative and programmatic requirements) is scheduled to be completed by September 2000.
- (2) The staff has recently prepared and provided comments to the Commission on DOE's Draft Environmental Impact Statement (DEIS) for a geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste at Yucca Mountain. The comments should enhance the DOE application for a license for a repository. The NRC provided technical comments in reports on specific technical issues and in comments on DOE's Viability Assessment in June 1999.

- (3) 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.

**United States Nuclear Regulatory Commission  
Risk-Informed Regulation Implementation Plan**

**February 2000**

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## **Executive Summary**

[Executive Summary to be added in next RIRIP update]

# Risk-Informed Regulation Implementation Plan

## Part I - General Process for Risk-Informing Agency Regulatory Activities

### 1. Introduction

NRC's Strategic Plan provides direction for current and planned initiatives for change to support the agency's transition to a risk-informed and performance-based environment. That plan defines strategic and performance goals, as well as performance measures, to guide the agency's work.

Among these broad strategies are those that relate to NRC work in risk-informed regulation.<sup>1</sup> That work has been underway for a number of years, and has involved the development of basic agency policy on the use of PRA in regulation (the 1995 PRA Policy Statement), the execution of this policy by a series of agency programs, and the coordination and documentation of plans for these projects in a single agency document (the PRA Implementation Plan) and the application of program results to licensee safety programs.<sup>2</sup>

While the Strategic Plan strategies provide general guidance for using risk information to improve regulation, more detailed and specific information is needed to describe the overall agency plan for deciding what, how, and when to risk-inform its regulations and regulatory processes. This information includes describing:

- the process and criteria for identifying those regulations and regulatory processes to be risk-informed;
- the priorities for allocating resources among specific risk-informed activities;
- the detailed work plans (tasks and schedules), including the development of associated needed guidance, methods, data, training, and communications mechanisms; and
- measures of success used in guiding a risk-informed approach for a specific regulatory process.

The purpose of this Risk-Informed Regulation Implementation Plan (RIRIP) is to provide this more detailed description and to serve as a focus for integrating the Commission's risk-informing activities. This plan extends (and replaces) the descriptions of staff activities provided

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<sup>1</sup> "Risk-informed regulation" is a term used to describe NRC's work to revise its regulations and regulatory processes so that the regulatory burden imposed by individual regulations or processes is commensurate with the importance of that regulation or process to protecting public health and safety and the environment.

<sup>2</sup> The nature of a number of these risk-informed programs is such that they may be voluntarily applied by licensees and not imposed on all licensees.

in the PRA Implementation Plan, in that it directly links these projects to the agency's Strategic Plan and explicitly defines the processes whereby all agency risk-informed regulatory activities are considered and priorities established for ongoing and future work in this area. This plan is also intended to serve as a communications tool to describe overall agency activities, philosophy and approach to risk-informed regulation.

This plan is organized into two major parts. The first part describes the Commission's philosophy and overall objectives in undertaking to risk-inform its regulatory processes. It also describes the process for prioritizing the schedules and resources allocated to specific regulatory changes and summarizes the status and results of the prioritization process. The second part provides detailed information on specific staff activities being undertaken to accomplish the Commission's objectives. This second part is broadly organized along the lines of the Commission's Strategic Plan, e.g., by Nuclear Reactor Safety Arena, Nuclear Materials Safety Arena, and Nuclear Waste Safety Arena.<sup>3</sup> Specific regulatory activities which are being risk-informed within each arena are described, as are specific staff programs within each activity. Specific tasks are identified for each program and significant future milestones presented for each. Progress in completing established milestones is also provided in the Plan's Executive Summary (to be included in later versions).

It must be recognized at the outset that the specific risk-informing strategies and tasks presented in this report may be, for each strategic arena, substantially different in both scope, form and content. This fact reflects the varied nature of the activities being regulated and the vastly different states-of-the-art of PRA methods that can presently be applied to each of these regulated activities.

It should also be noted that this report condenses and summarizes the more detailed descriptions of staff work that are found in specific program plans, Commission papers and in the operating plans of each office. Consequently, references are made in this plan to other supporting documentation in lieu of reproducing that information here.

## **2. Purpose of Risk-Informed Regulation Initiatives**

The Commission's PRA Policy Statement, published in 1995, provides the fundamental guidance by which the staff is undertaking its initiatives to risk-inform its regulatory activities. The Policy Statement states 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.

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<sup>3</sup> This version of the RIRIP describes a subset of staff activities, providing an example of the plan, for work in the Nuclear Reactor Safety Arena. Work in the Nuclear Materials and Nuclear Waste Safety Arenas will be added to the RIRIP as plans in these arenas are further developed.

- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.
- PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.
- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: foremost, through safety decision-making enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burden on licensees.

These Commission policies and expectations have been used by the staff to define the prioritization process and criteria used to decide which regulatory activities to risk-inform (and when they will be risk-informed). In addition, these policies and expectations are being used to determine how best to risk-inform each specific regulatory activity.

### **3. Guidelines for Selection and Implementation of Risk-Informed Activities<sup>4</sup>**

#### **3.1 Process for Identification of Regulatory Activities to be Risk-informed**

This section will summarize the elements of and criteria used in the process for identifying needed changes to regulations and regulatory processes. That process will consist of a systematic examination of current regulations and regulatory processes, using evaluation criteria based on the four agency performance goals. Example criteria could include:

- Maintain safety
- Increase public confidence
  - The change improves the clarity and consistency of agency requirements.

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<sup>4</sup> This section summarizes the staff's initial approach for prioritizing activities. Additional detail on this process will be developed and documented in the next RIRIP update.

- Improve effectiveness, efficiency, and realism
  - The change makes use of currently available or readily developed PRA methods and associated data.
  - The agency costs to implement the change are small relative to the estimated resource savings.
- Reduce unnecessary burden
  - Stakeholders have identified the change as potentially reducing burden while maintaining safety.

The results of this identification and evaluation process will be used in the agency's Planning, Budgeting, and Performance Management process, in which more detailed resource allocations will be made.

### **3.2 Results of Prioritization**

This section will summarize the results of the staff's prioritization of regulatory activities, using the process described in Section 3.1. The staff expects to provide this information in one or more tables which will describe:

- Regulatory activities which have been identified as high priority and are being currently risk-informed;
- Regulatory activities which have been identified as high priority and are planned to be risk-informed in the future; and
- Regulatory activities which have been prioritized as being not appropriate to be risk-informed.

This set of tables will be provided in future versions of this plan.

### **3.3 Assessing the Success of Staff Risk-Informing Efforts**

The process for identifying regulatory activities to be risk-informed will also include an assessment of the staff's success in changing these activities. The staff will develop metrics for measuring the success of its work and, after regulatory activities are changed, will evaluate the results of its work and make any necessary improvements.

## Part II - Specific Implementation Plans

### 4. Plans for Implementation of Risk-Informed Regulation - Nuclear Reactor Safety Arena

#### 4.1 General Guidance for Risk-Informing Nuclear Reactor Safety Regulatory Activities

This section describes efforts to risk-inform requirements for the design, construction, operation and oversight of licensed nuclear power reactors. These efforts include consideration not only of revisions to the specific sections of Commission regulations, but revisions to supporting appendices (including the General Design Criteria of 10CFR50), Standard Review Plan sections, Regulatory Guides and Branch Technical Positions. This effort also includes Option 1 (on-going rulemaking efforts), Option 2 (to risk-inform operationally related requirements) and Option 3 (a study to determine areas where other, primarily design-related, requirements could be risk-informed). Also included is the issuance of implementing guidance on the uses of PRA in support of specific licensing and inspection activities, in monitoring and reporting on plant performance, in training the staff and in communicating Commission plans for regulatory changes with appropriate stakeholders.

NRC's Strategic Plan<sup>5</sup> defines strategic and performance goals and establishes performance measures to guide the agency's work in risk-informing its requirements in the Nuclear Reactor Safety strategic arena. Some of these strategies relate to NRC work in risk-informed regulation in this arena. These specific performance goals and strategies are:

**PERFORMANCE GOAL: Maintain safety, protection of the environment, and the common defense and security.**

The NRC will employ the following **strategies** to maintain safety and the protection of the environment and to promote the common defense and security:

- *We will evaluate operating experience and the results of risk assessments for safety implications.*
- *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

**PERFORMANCE GOAL: Increase public confidence.**

The NRC will employ the following **strategies** to increase public confidence:

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<sup>5</sup> Strategies described here are reproduced from NUREG-1614 (draft), Volume 2, Part 1.

- *We will communicate more clearly. We will add more focus, clarity, and consistency to our message, be timely, and present information in the proper context with respect to the risk of the activity.*

**PERFORMANCE GOAL: Make NRC activities and decisions more effective, efficient, and realistic.**

The NRC will employ the following **strategies** to make NRC activities and decisions more effective, efficient, and realistic:

- *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

**PERFORMANCE GOAL: Reduce unnecessary regulatory burden on stakeholders.**

The NRC will employ the following **strategies** to reduce unnecessary regulatory burden on stakeholders:

- *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

#### 4.2 Reactor Safety Activities and Risk-Informed Modifications

Those high priority risk-informing activities identified in Section 3.2 relate to four Nuclear Reactor Safety Arena activities. These areas are (1) basic risk-informing principles, goals and standards, (2) reactor oversight, (3) reactor licensing, and (4) reactor rulemaking (modifications to specific rules). Within each of these activities are specific programs (e.g. Modification of Part 50 Technical requirements). Tasks for completing each program are then described along with completion dates for each task. These tasks are of several types, namely:

Intended Outcome- <sup>6</sup>	These task types are generally those that represent the final outcome of the activity, e.g., issuance of a final rule.
Guidance-	This task type includes work designed to provide needed guidance to both staff and licensees defining processes, acceptance criteria and analytic methods deemed acceptable by the NRC staff as support for licensing actions
Methods, Tools and Data	Tasks in this group are designed to provide and improve methods, data and analyses needed to apply risk insights to specific technical issues and other regulatory decisions

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<sup>6</sup> Tasks will be explicitly identified by type in the next version of the RIRIP.

Training Needs	This task type includes needed training, development of training material, and implementation of training classes
Communications Mechanisms	<p>Because of the importance of communicating Commission plans and programs to internal and external stakeholders in achieving the objectives of risk-informed regulation, tasks that provide for such communication are identified. In regard to communications, it is important to note that the staff intends to obtain external stakeholder input on this work in several ways, including:</p> <ul style="list-style-type: none"> <li>• Public workshops scheduled at critical milestones:</li> <li>• Periodic interactions with the ACRS</li> <li>• Use of pilot studies</li> <li>• Website updates providing key information on the staff's work</li> </ul> <p>In parallel, the staff will communicate with internal stakeholders via meetings and training sessions to discuss the work underway, obtain needed input, and discuss results.</p> <p>The staff also will also provide periodic status reports to the Commission on its work and its interactions with stakeholders.</p>

To further illustrate the inter-relationship between various risk-informing activities described in this plan, Table 4.1 has been prepared to show where, in this report, specific information can be found and further, to cross-link the various activities being carried out with those supporting elements needed to achieve program goals. More detailed information on staff plans for these changes is provided in the following sections.

#### **4.2.1 Risk-Informed Safety Principles, Goals, and Standards**

##### **Overview**

The staff presently uses several Commission policy statements and other documents to guide their work to risk-inform reactor safety regulatory activities. These include the PRA Policy Statement, the Safety Goal Policy Statement, Regulatory Guide 1.174, and Standard Review Plan Section 19. This guidance continues to evolve with time to reflect new Commission decisions and priorities, advances in PRA technology, and other changes. Such changes may lead to the identification of the need for new general guidance documents. This section describes work being performed by the staff to maintain general risk-informed reactor safety guidance documents and, as needed, to develop new general guidance documents.

Guidance documents implementing this general guidance with respect to a specific application are described in the associated application-specific sections of the RIRIP.

Table 4.1<sup>7</sup>

Key Elements of Implementation Plan for Nuclear Reactor Safety Arena								
Regulatory Activity / Element	Priority	PBPM Cycle (for activities not yet started)	Report Section	Intended Outcome	Guidance	Methods, Tools, and Data	Communications Mechanisms	Training Needs
<b>Safety Principles and Goals</b>			4.2.1					
Modification of safety goal policy			4.2.1.1					
Update of RG 1.174 and SRP Section 19			4.2.1.2					
Development of PRA standards			4.2.1.3					
<b>Oversight</b>			4.2.2					
Revised reactor oversight process			4.2.2					
<b>Licensing Actions</b>			4.2.3					
Amendment and exemption reviews			4.2.3.1					
Staff authority to assess risk			4.2.3.2					
Update application specific RG/SRP			4.2.3.3					
<b>Rulemaking</b>			4.2.4					
Scope of Part 50 special treatment requirements			4.2.4.1					
Part 50 technical requirements			4.2.4.2					
Pressurized thermal shock			4.2.4.3					
Fire protection			4.2.4.4					

<sup>7</sup>

Table 4.1 is intended, for this version of the RIRIP, to provide an example of the agency's risk-informed reactor safety activities. This table will be filled out in future versions of the RIRIP.

## **Tasks and Milestones**<sup>8</sup>

### **4.2.1.1 Modifications to the Safety Goal Policy Statement**

In the past several years, the ACRS and the staff have identified a set of potential changes to the Commission's 1986 Safety Goal Policy Statement. The staff's work, described in SECY-97-208, SECY-98-101, and SECY-99-191, is intended to provide recommendations on the need for such changes. Specific staff actions and schedules for completing this work are provided below:

- Provide recommendations to Commission on needed changes to Safety Goal Policy Statement 3/00

### **4.2.1.2 Update and Modification of Regulatory Guide 1.174 and SRP Section 19**

In 1998, the NRC issued general guidance on the use of risk information in staff reviews of proposed license amendments<sup>9</sup> (Regulatory Guide 1.174 and Standard Review Plan Section 19). This guidance is periodically reviewed and updated to reflect new Commission guidance, staff experience, and other new information. Specific staff actions and schedules for reviewing and updating these documents are:

- Complete initial revision of RG 1.174/SRP 19 5/00
- Complete ACRS/CRGR review of initial version of RG 1.174 6/00
- Provide second annual RG1.174/SRP 19 review to Commission 6/00
- Issue draft of RG 1.174/SRP 19 for public comment 8/00
- Revise 1.174 per public comment 11/00
- Provide recommended final version of RG 1.174/SRP 19 to Commission 01/01

### **4.2.1.3 Support for Development of Consensus PRA Standards**

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<sup>8</sup> The tasks and milestones shown in the remainder of this section are a partial set, showing only key technical and communication milestones. These are drawn principally from the Chairman's Tasking Memorandum.

<sup>9</sup> While these documents were specifically written with respect to one regulatory activity - license amendments - they have been found to provide guidance useful to many other regulatory activities. As such, they are considered to be more general guidance documents, and included in this section.

The increased use of probabilistic risk assessments in the regulatory decision-making process requires consistency in the quality, scope, methodology and data used in such analyses. These requirements apply to PRAs developed by industry to support specific, risk-informed licensing actions as well as to PRAs developed by NRC staff to analyze specific technical issues or to support risk-informed Commission decisions. To this end, NRC has been working with the American Society of Mechanical Engineers (ASME) to develop a national consensus standard setting forth specific guidance regarding the construction and execution of a PRA covering internal initiating events (Level 1). When developed, such a standard will help to ensure that PRAs developed in accordance with this standard are robust, consistent, and defensible and are documents upon which regulatory decisions can confidently be made. While the ASME maintains overall responsibility for this effort, active NRC and industry participation has been, and will continue to be, essential to the development of such a standard. In parallel, the staff has been working with the National Fire Protection Association (NFPA) to develop standards for fire risk analysis.

More recently, the NRC staff has been working with the American Nuclear Society (ANS) to develop a companion standard covering probabilistic analyses that would include the progression of severe accidents, the impacts of external events on plant risk and risk-significant events that could occur when a plant is operating at low power or when shutdown (LP/SD).

Again, recognizing that control of these projects properly rests with the ASME and the ANS, the following milestones have been established by these organizations:

- |   |                             |
|---|-----------------------------|
| • Draft PRA standard issued for comment by ANS                    | Seismic 6/00<br>LP/SD 9/00  |
| • PRA standard comments received by ANS and final draft developed | Seismic 9/00<br>LP/SD 12/00 |
| • Final PRA standard issued by ASME                               | 1/01                        |
| • Final fire PRA standard issued by NFPA                          | 3/01                        |
| • Final PRA standard issued by ANS                                | Seismic 6/01<br>LP/SD 6/01  |

#### **4.2.2 Risk-Informed Modifications to the Reactor Oversight Process**

##### **Overview**

As discussed in SECY-99-007 and SECY-99-007A and related SRMs, the Commission has committed to revamping its oversight process for commercial nuclear power plants. The new program takes into account improvements in the performance of the nuclear industry over the past twenty years, the intent of the NRC to apply more objective, timely, and safety-significant criteria in assessing performance, as well as the agency's need to effectively regulate the industry with less resources.

The broad objectives of this effort are to provide a regulatory oversight framework that will:

- Ensure that plants continue to operate safely.
- Focus agency actions on those activities of greatest risk significance making more efficient use of agency and licensee resources.
- Apply greater regulatory attention to facilities with performance problems and reduce regulatory attention on facilities that perform well.
- Use more objective measurements to assess the performance (e.g., using “performance indicators”) of nuclear power plants where appropriate.
- Provide the nuclear industry and the public timely and understandable assessments of plant performance.
- Respond to violations of regulations in a predictable and consistent manner that reflects the safety impact of the violations.
- Enhance public confidence by increasing predictability, consistency and objectivity of the oversight process.

### **Tasks and Milestones**

The new oversight process, developed using a risk-informed approach, will establish baseline inspection programs common to all nuclear plants. This program will focus on plant activities and systems that have the potential to initiate an accident or to increase the consequences should an accident occur. Areas subject to this baseline inspection program have been selected because of their importance from the point of view of potential risk, past operational experience and regulatory requirements.

Specific tasks being undertaken in support of this revised oversight process are presented below.

- |  |      |
|--|------|
| • Issue Commission paper and brief Commission on the revised reactor oversight process, results of the pilot program and staff recommendation for initial implementation | 3/00 |
| • Complete NRC training and licensee workshop on new reactor oversight process in preparation for full implementation  | 4/00 |
| • Commence initial implementation of new reactor oversight process at all operating sites  | 4/00 |
| • First agency Action Review Meeting to discuss agency response for plant performance assessment inputs using the revised reactor oversight process                      | 5/01 |
| • Complete evaluation of implementation and effectiveness of the first year of implementation of the revised reactor oversight process                                   | 6/01 |

### 4.2.3 Risk-Informed Modifications to Reactor Licensing Actions

#### Overview

One of the first applications of the Commission-defined goals in the PRA Policy Statement was to define a new, risk-informed, voluntary approach to the reactor license amendment process. The intent of this change was to more clearly define how PRA methods and results could be used to help assess the safety significance of proposed license amendments which potentially would reduce regulatory requirements in specific areas of plant operations. The staff concluded that guidance on how to use risk information in such situations was needed by both licensees and staff reviewers.

RG 1.174 and SRP Section 19, described in Section 4.1.2 , provide general guidance on risk-informed licensing actions. In addition to these general guidance documents, the staff developed a series of regulatory guides and SRP sections that provided more specific guidance on risk-informed inservice testing, graded quality assurance, technical specifications, and inservice inspection (ISI) of piping. In SECY-98-067, the staff proposed final versions of these documents (except for the ISI documents). The Commission approved publication in an SRM dated June 29, 1999. In SECY-97-190, the ISI regulatory guide and SRP section were provided to the Commission as proposed drafts for trial use. The Commission approved that staff proposal in an SRM dated October 1, 1997.

Since completion of the guides, the licensees and the staff have been applying them in specific license amendment requests. In addition, the staff performs an annual review of these guides, compiling experience with their use, and proposing modifications wherever indicated.

#### Tasks and Milestones

##### 4.2.3.1 Licensing Reviews

As noted in SECY 99-256, the staff has under consideration a number of specific licensing actions and requests from licensees for exemptions from current regulatory requirements based on risk considerations. The staff is continuing to process and evaluate these requests based, among other things, on the criteria set forth in RG 1.174. Specific staff actions and schedules for this work are:

- Safety Evaluation Report (SER) to be issued on Waterford 3 application for diesel-generator allowed outage time (AOT) extension. 4/00
- SER to be issued on Waterford 3 application for containment spray system AOT relaxation. 5/00
- SER to be issued on Waterford 3 application for low pressure safety injection system AOT relaxation 5/00
- SER to be issued on the South Texas Project request for multiple exemptions to exclude certain components from the scope of

special treatment requirements in the regulations. 6/00

- SER to be issued on Combustion Engineering Owners Group Joint Applications Report for Containment Isolation Valve AOT Relaxation for 8 sites. 6/00

#### 4.2.3.2 Licensing Guidance

Before risk-informed revisions are made to the full scope of reactor regulations, interim guidance must be developed to support both the industry and Commission staff in applying risk considerations to current and near term licensing actions. The following tasks have been identified in the EDO's February 14, 2000, memorandum to the Commission.

##### Guidance on Staff Authority

- Issue Regulatory Issue Summary (RIS) describing interim guidance 3/00
- Develop modifications to RG1.174 and SRP Chapter 19 regarding risk-informed decision making
  - Transmit draft modifications to ACRS, CRGR, and issue for public comment 4/00
  - Meet with stakeholders, ACRS, and CRGR 5/00
  - Resolve comments and transmit proposed final modifications to ACRS and CRGR 7/00
  - Meet with ACRS and CRGR on proposed final modifications 8/00
- Develop modification to NRR Office Letter 803 9/00
- Transmit final modifications to the Commission 9/00
- Issue RIS describing final guidance ~1 month after Commission consent

Other guidance development tasks include:

##### Guidance on Risk-Informed Inservice Inspection

- Complete ASME code case reviews 6/00
- Complete evaluation of industry methods 12/00

- Provide recommended version of RG 1.178/SRP to Commission 12/01

#### Annual Reviews

- Complete second annual application-specific RG/SRP review and provide to Commission 8/00

#### **4.2.4 Risk-Informed Modifications via Rulemaking**

The achievement of the PRA Policy Statement goals for some regulatory activities may best be accomplished by changes to agency regulations. A number of such changes have been initiated and are discussed in more detail below. These changes may result in alternative implementation mechanisms for current regulations, which maintain safety but could be voluntarily undertaken by licensees to reduce unnecessary burden.

##### **4.2.4.1 Risk-Informed Modifications to Regulated Scope Requirements**

#### Overview

In SECY-99-256, the Commission was provided with a rulemaking plan for modifying special treatment requirements for structures, systems and components (SSCs), including a proposed new rule (10 CFR 50.69) and a new appendix to 10 CFR 50 (Appendix T). The voluntary alternative approach would vary treatment of SSCs on the basis of their safety significance using a risk-informed categorization method. In SECY-99-256, the staff recommended the Commission approve the publication of a Advance Notice of Proposed Rulemaking (ANPR) setting forth the details of the staff's proposal for public comment. The Commission approved the staff's recommendations in an SRM dated January 31, 2000. The ANPR will be published in the Federal Register in March 2000.

#### Tasks and Milestones<sup>10</sup>

- Publish ANPR for public comment 3/00
- Hold public workshop on ANPR comments 4/00
- Complete review of public comments on ANPR 5/00
- Hold public workshop on draft proposed rulemaking 7/00
- Submit proposed rulemaking to Commission 9/00
- Complete categorization pilot program (issue exemptions) 7/01

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<sup>10</sup> The staff is currently evaluating the overall schedule for this regulatory activity considering the delays to date in receiving a Commission SRM and receiving the NEI guidance, and to reflect difficulties in getting commitments to the pilot program.

- Submit final rulemaking to Commission 10/01
- Publish final rulemaking 3/02

#### **4.2.4.2 Risk-Informed Modifications to Technical Requirements**

##### **Overview**

In SECY-99-264, dated November 8, 1999, the staff proposed a two-phase approach to examining the technical requirements of 10 CFR 50 for possible change to make them more risk-informed. The Commission approved this approach in an SRM dated February 3, 2000. Phase 1 will consist, first, in a systematic examination of the technical requirements of 10CFR50 as well as supplementary guidance provided in related regulatory guides and standard review plan sections. Candidate requirements for change will then be identified on the basis of a set of evaluation criteria. Examples of such criteria, as set forth in SECY 99-264, may take the form of (a) frequencies of initiating event scenarios covered by the specific set of regulatory requirements and guidance documents, (b) the risk contributions of those scenarios and related SSCs and (c) the degree of conservatism (excessive or non-conservative) in associated methods, assumptions or acceptance criteria set forth in those requirements.

For those candidates identified as having a high priority, specific changes will be developed and proposed for Commission consideration. Those changes will reflect an assessment of the technical bases upon which those requirements were initially established and the adequacy of the technical base needed to adequately support a rulemaking change and/or changes in identified guidance documents. Changes thus proposed should provide an improved balance among needed safety margins, defense-in-depth, risk and resource requirements. Pilot programs to demonstrate the feasibility of identified changes will be carried out, where practical, before final implementation.

Phase 2 of this process will consist of the formulation and execution of specific rulemaking actions consistent with established Commission administrative procedures. These actions may be done together at the conclusion of the study program or individually if it is determined that significant benefits, either in terms of improved safety or burden reduction, would result from prompt action.

As noted earlier, this process may ultimately result in relaxation of certain requirements and/or the addition of requirements that the staff believes are warranted.

##### **Tasks and Milestones**

- Hold public workshop on results of trial application of prioritization process 2/00
- Provide status report to Commission 3/00
- Identify preliminary set of proposed changes and recommendations 8/00

- Hold public workshop on preliminary set of proposed changes and recommendations 9/00
- Final report to Commission 12/00

#### 4.2.4.3 Risk-Informed Modifications to Pressurized Thermal Shock Requirements

##### Overview

The staff has initiated a program to revisit the technical bases for the Pressurized Thermal Shock (PTS) Rule (10CFR50.61) and, potentially, to propose a revision to that rule that would significantly reduce any unnecessary level of conservatism in the rule. This effort has been undertaken as a full-participatory activity where active participation by the public and industry in evaluating the changes in the relevant technologies has been sought. In the past several years, new research information has resulted in an improved analytical capability to evaluate PTS events. Results from recent preliminary evaluations are encouraging with respect to the potential to substantially reduce the conservatisms in the PTS screening criterion and in developing a comprehensive risk-informed performance-based method. This method will be used by the staff to perform structural integrity analyses of the pressure vessel and estimate plant risks from potential PTS events. This new information, if consistent with the preliminary evaluations, will be used to provide the technical basis for a new version of the rule.

##### Tasks and Milestones

- Present to ACRS the methodology to perform PTS risk analysis 3/00
- Present to ACRS the revised PTS risk acceptance criterion 3/00
- Develop revised PTS risk acceptance criterion 5/00
- Conduct public workshops to identify and resolve open questions on analysis procedures and inputs in probabilistic fracture mechanics, thermal hydraulics and PRA areas 5/00
- Present to ACRS the PTS risk analysis of the selected PWR plants 9/00
- Develop Integrated PTS risk estimate for a generic PWR plant 10/01
- Present to ACRS the technical basis for proposed changes in 10 CFR 50.61 PTS screening criterion 12/01

Milestones regarding subsequent NRR actions to revise the PTS Rule are being developed and will be included in future revisions of the Implementation Plan.

#### 4.2.4.4 Risk-Informed Modifications to Fire Protection Requirements

##### Overview

The staff has developed a rulemaking plan, described in SECY-00-0009, to revise NRC's existing deterministic fire protection regulations. This plan will ultimately result in NRC endorsement of a risk-informed, performance based consensus standard being developed by the National Fire Protection Association (NFPA Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants"). Such endorsement would allow licensees to use this standard as a voluntary alternative to NRC's existing fire protection requirements. This approach was initially endorsed by the Commission in its SRM dated June 30, 1998, responding to SECY 98-058.

##### Tasks and Milestones

- Hold public meeting with interested stakeholders 4/01
- Brief ACRS fire protection subcommittee on rulemaking efforts 5/01
- Brief CRGR on rulemaking efforts 6/01
- Publish proposed rule change for public comment 7/01
- Resolve public comments 11/01
- Brief ACRS & CRGR on final rule 1/02
- Submit final rule for Commission approval 3/02