

POLICY ISSUE INFORMATION

October 25, 2006

SECY-06-0217

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: IMPROVEMENT TO AND UPDATE OF THE RISK-INFORMED REGULATION
IMPLEMENTATION PLAN

PURPOSE:

To provide the Commission with the staff's response in part to the staff requirements memorandum (SRM) M060503B, "Briefing on Status of Risk-Informed and Performance-Based Reactor Regulation," dated June 1, 2006, which directed the staff to: (1) improve the risk-informed regulation implementation plan (RIRIP) so that it is an integrated master plan for activities designed to help the agency achieve the Commission's goal of a holistic, risk-informed, and performance-based regulatory structure; and (2) seek ways to communicate the purpose and use of probabilistic risk assessments (PRAs) in the U.S. Nuclear Regulatory Commission's (NRC's) reactor regulatory program more transparently to the public and stakeholders. In addition, this paper: (1) summarizes the significant risk-informing accomplishments completed over the past 6 months and activities planned for completion over the next 6 months; and (2) provides the semiannual RIRIP update.

BACKGROUND:

In 1995, the Commission issued a policy statement regarding the use of PRA methods in nuclear regulatory activities. One purpose of the policy statement was to assure that the many potential applications of PRA were implemented in a consistent and predictable manner that would promote regulatory stability and efficiency. The policy statement directed that the use of

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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. In addition, the policy statement directed that the agency should use PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) 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.

In a January 2000 memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. That strategy evolved into the initial RIRIP, which the staff provided to the Commission in 2000. The Commission reviewed the plan and, after a briefing by the staff in March, directed the staff in April 2000 to include in the next RIRIP update an internal communications plan, staff training requirements, and a discussion of internal and external factors that may impede risk-informed regulation. The staff issued the first complete version of the RIRIP in October 2000. Since then, various other interactions between the Commission, staff, and stakeholders have culminated in the latest version of the RIRIP (SECY-06-0089), which was issued on April 18, 2006.

On May 3, 2006, the NRC staff and representatives of the nuclear power industry briefed the Commission on the status of risk-informed and performance-based reactor regulation. As discussed during that meeting, significant progress has been made on the agency's risk-informed initiatives, but much work remains to be done. On June 1, 2006, the Commission issued an SRM M060503B which directs the staff to (1) improve the RIRIP so that it is an integrated master plan for activities designed to help the agency achieve the Commission's goal of a holistic, risk-informed, and performance-based regulatory structure, and (2) seek ways to communicate more transparently the purpose and use of PRAs in NRC's reactor regulatory program to the public and stakeholders.

DISCUSSION:

This paper provides the staff's response to the June 1, 2006, SRM on improving RIRIP (Enclosure 1) and on identifying ways to communicate the purpose and use of PRAs more transparently. In addition, this paper summarizes the significant risk-informing accomplishments completed over the past 6 months and those activities planned for completion over the next 6 months (Enclosure 2), and the semiannual RIRIP update (Enclosure 3). The semiannual RIRIP update provided to the Commission in April 2007 will reflect the improvements discussed in this paper.

RIRIP Improvements

The staff believes that the RIRIP should continue to serve as the vehicle to coordinate the staff's activities in implementing the Commission's 1995 PRA policy statement. As such, the RIRIP should document the staff's plans to achieve that vision, and identify the regulatory requirements and practices to be risk informed and the necessary data, methods, guidance, and training to be developed.

The NRC's PRA Steering Committee (PRASC)¹ (composed of the Office Directors of Nuclear Material Safety and Safeguards, Nuclear Reactor Regulation, Nuclear Regulatory Research, Nuclear Security and Incident Response; the Director of the Office of Enforcement; one Regional Administrator; and a representative of the Office of the General Counsel) met to (1) review the steering committee's charter in relation to RIRIP and (2) evaluate options for improving RIRIP in response to the Commission's SRM. The PRASC concluded that the improvements should focus on the up-front RIRIP planning process and on the back-end following completion of RIRIP activities through the addition of an effectiveness review process.

With regard to the RIRIP planning process, for the past several years, the RIRIP has focused on two of the NRC's performance goals (i.e., safety and effectiveness) discussed in the Strategic Plan for fiscal year (FY) 2004–2009. This structure links the various RIRIP activities being pursued and strategies discussed in the Strategic Plan; however, it does not facilitate a clear understanding of how these activities contribute, either individually or collectively, toward achievement of a particular risk-informed vision or specific risk-informed goals.

The NRC's core business is aligned along 3 arenas (i.e., reactors, materials, and waste), and within each arena, the NRC performs its activities in 3 functional areas (i.e., oversight, licensing/certification, and rulemaking and guidance development). To improve the RIRIP, the staff believes that a risk-informed vision needs to be defined for each arena, and specific goals developed for each functional area.

Historically, the reactor arena has encompassed NRC's activities associated with the following categories of reactors: operating reactors, new reactors (i.e., near-term early site permits, combined licenses, and design certifications), and advanced reactors (i.e., non-light-water reactors). Within the RIRIP, the staff concludes that it may be necessary to separate the reactor arena for these reactor categories to facilitate development of a clear vision and specific goals. This is due to the large difference in the extent to which these reactor categories could feasibly be risk-informed and performance-based. For example, in response to the Commission's SRM relating to SECY-05-130, "Policy Issues Related to New Plant Licensing and Status of the Technology-Neutral Framework for New Plant Licensing," the staff is considering the spectrum of issues relating to risk-informing the reactor requirements for advanced reactors, and is to integrate safety, security, and preparedness throughout this effort. This could provide a coherent risk-informed and performance-based regulatory structure for advanced reactors.

Similarly, the staff will consider whether the materials and waste arenas need to be further separated within the RIRIP to recognize any fundamental differences that impact the extent to which they can be risk-informed.

To develop the vision and goals, the staff will perform an assessment of where the agency should take risk-informed regulation in the short term (i.e., 1–5 years) and, if possible, the long term (i.e., 5–10 years). This assessment will factor in Commission guidance and input received

¹The NRC recently reorganized the Offices of Nuclear Reactor Regulation and Nuclear Material Safety and Safeguards. As a result, the PRASC will be reconstituted to reflect the new organization. In addition, the next semi-annual RIRIP update will reflect the new organizations.

from stakeholders. The staff will use the resulting vision and goals to assess current RIRIP activities to determine what activities should continue, what activities should be sunset, and what new activities are needed. The staff will restructure the RIRIP around these arenas to facilitate a clear understanding of the agency's plan. For each activity that is determined to be necessary to meet the vision and goals, the staff will develop a program plan that contains specific milestones and deliverables.

The staff anticipates that there will be significant differences in the vision and goals established for the various arenas because of such factors as (1) the inherent major differences in the complexities and risk associated with NRC-regulated licensed activities (e.g., a nuclear power plant versus a sealed radioactive source), (2) the state-of-the-art with regard to PRA technology and methods (i.e., PRA methods are relatively well developed for the reactor arena versus the materials and waste arenas), (3) the level of commitment of stakeholders in the various arenas interested in pursuing risk-informed activities, and (4) the potential cost and benefits associated with adoption of risk-informed approaches.

With regard to the back end, the RIRIP currently does not have an integral effectiveness review process built into it. Therefore, the staff is developing a process with the goal of determining whether the desired outcomes from the various RIRIP activities were achieved and, if not, why not. The effectiveness review process will identify lessons learned from completed RIRIP activities that should be adopted as best practices for future activities. In addition, the effectiveness review will look to identify barriers to the further use of risk-informed regulation.

Enclosure 1 provides additional information on the staff's plan to develop a better RIRIP planning process and effectiveness review process.

Communicating the Purpose and Use of PRAs

In response to the Commission's direction in SRM M060503B to seek ways to communicate more transparently the purpose and use of PRAs in NRC's reactor regulatory program to the public and stakeholders, the staff is (1) redesigning the NRC public website to make information on NRC's risk-informed initiatives and PRA applications easier to locate and understand, (2) developing a web-based interface to allow the staff to update the RIRIP activities more timely and efficiently, and (3) implementing an RIRIP Openness Strategic Plan Goal (OP-1) to improve the NRC's ability to communicate complex information on risk-informed regulation.

The staff expects that information from the redesigned website will improve the quality of the RIRIP. The website will also include an easy-to-understand tutorial on PRA technology and risk, as well as a section highlighting key risk-informed initiatives being undertaken by the various program offices. Updates to the public website will replace Enclosure 3 starting with the April 2007 RIRIP Paper. The staff will develop a communications plan to roll out the new website.

Semiannual RIRIP Update and Significant Accomplishments

Enclosure 2 summarizes the highlights of the major risk-informing activities that the staff has completed over the past 6 months and those activities that are scheduled for completion over the next 6 months. Enclosure 3 provides the semiannual RIRIP update.

COMMITMENTS:

The staff will update the Commission on progress made in implementing the RIRIP improvements proposed in this paper and a status on the development of an integrated Master Plan in the next semiannual RIRIP update. The staff will maintain the schedule for conducting effectiveness reviews in the RIRIP. The staff will develop and implement a communications plan associated with rolling out the new website.

RESOURCES:

In response to the Commission's direction regarding the October 2000 version of the RIRIP, the updated plan lists the priority rating of each risk-informed regulation implementation activity. The staff determined these priorities through the FY 2008 planning, budgeting, and performance management (PBPM) process, according to a common prioritization methodology developed by the program offices and used to derive a prioritized listing of planned activities. Resources for RIRIP activities—except those activities noted as being deferred (i.e., "on hold")—have been budgeted in FY 2007 and for FY 2008. The Office of Nuclear Regulatory Research has 0.5 FTE in its budget to coordinate the RIRIP. Currently, effectiveness reviews are not budgeted. Once a process is identified, funds will be requested via the PBPM process.

COORDINATION:

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

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Enclosures:

1. Improvements to the Risk-Informed Regulation Implementation Plan
2. Highlights of Major Risk-Informing Activities
3. Risk-Informed Regulation Implementation Plan

IMPROVEMENTS TO THE RISK-INFORMED REGULATION IMPLEMENTATION PLAN

Purpose

The purpose of this enclosure is to respond to the Commission's June 1, 2006, staff requirements memorandum (SRM) M060503B resulting from the May 3, 2006, Commission briefing on the "Status of Risk-Informed and Performance-Based Reactor Regulation." In that SRM, the Commission stated the following:

The staff should improve the risk-informed regulation implementation plan (RIRIP) so that it is an integrated master plan for activities designed to help the agency achieve the Commission's goal of a holistic, risk-informed and performance-based regulatory structure. The plan should continue to give priority to risk-informed activities underway and incorporate lessons learned from earlier activities as appropriate.

Background

In SECY-00-0213, the staff provided the Commission with the first complete version of the RIRIP. As described in former-Chairman Jackson's letter of June 18, 1999, to Senator Thompson and others, the staff developed the RIRIP in response to a General Accounting Office recommendation. The first RIRIP was a plan that contained (1) a statement of objectives and their relevance to the probabilistic risk assessment (PRA) policy statement and the agency's Strategic Plan; (2) a set of criteria and a process for deciding what areas should be risk informed; (3) guidelines for risk-informed activities; (4) a summary of activities planned to implement the risk-informed regulatory strategies that are described in the agency's Strategic Plan; (5) a description of an internal communications plan for soliciting and considering staff input and feedback on the agency's plan and progress toward implementing risk-informed regulatory initiatives; (6) a description of a training program to ensure that the staff has the knowledge and skills needed to implement risk-informed regulations; and (7) success measures.

The RIRIP is intended to coordinate the staff's activities in implementing the Commission's 1995 PRA policy statement. In particular, the policy describes the Commission's vision that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the U.S. Nuclear Regulatory Commission's (NRC's) deterministic approach and supports the NRC's traditional defense-in-depth philosophy." Furthermore, the Commission indicated that 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. The RIRIP describes the staff's plans to achieve that vision by applying criteria to selected regulatory requirements and practices: applying risk-informed analysis to those requirements and practices; and developing the necessary data, methods, guidance, and training. The plan is also intended to explain the agency's activities, philosophy, and approach to risk-informed regulatory policy to internal and external stakeholders.

Discussion

The challenge in developing RIRIP over the years has been in identifying and specifying activities that are both necessary and sufficient to implement the Commission's PRA policy statement. For the past several years, the focus of RIRIP has been on two of the Nuclear Regulatory Commission's (NRC's) Strategic Plan goals (i.e., safety and effectiveness) and supporting strategies. The RIRIP activities support the NRC's programs in the reactor, materials, and waste arena; however, there are significant differences in the scope, form, and content of RIRIP activities underway in these various arenas. These differences result from the varying nature of the activities regulated and the availability and maturity of risk assessment methods and tools.

As discussed during the May 3, 2006, Commission meeting with the nuclear industry regarding risk-informed and performance-based regulation, the staff believes that risk-informed initiatives have enhanced all aspects of the NRC's regulatory programs and that steady progress is occurring in implementing the Commission's PRA policy and directions. However, the staff recognizes that the NRC's regulations and processes could be improved and better integrated. To implement the Commission's holistic, risk-informed, and performance-based regulatory structure, the staff concludes that a new framework is needed for RIRIP to provide an integrated master plan across NRC's business functional areas (i.e., licensing/certification, rulemaking/guidance development, and oversight).

In response to the SRM, the staff met with the NRC's PRA Steering Committee (PRASC), which is composed of the Office Directors of Nuclear Material Safety and Safeguards (NMSS), Nuclear Reactor Regulation (NRR), Nuclear Security and Incident Response (NSIR), Nuclear Regulatory Research (RES), and Enforcement (OE); one Regional Administrator; and a representative of the Office of the General Counsel (OGC). The steering committee meeting focused on reviewing its charter in relation to RIRIP and evaluating options for reinvigorating RIRIP in response to the Commission's direction. With regard to RIRIP, the PRASC is responsible for (1) providing strategic direction regarding use of PRA technology and risk information in regulatory matters in support of the agency's mission and (2) overseeing implementation of interoffice risk-informed regulation. The PRASC concluded that the NRC needed a better framework for planning RIRIP activities and assessing their effectiveness. The planning process should establish a clearer vision and specific goals for where the agency should be in risk-informing activities for the next 1–5 year period. In addition, where feasible, the agency should establish a vision and specific goals for the 5–10 year time period. The agency needs to establish these goals so that it can determine which RIRIP activities to perform and what resources are necessary. Once it has identified the vision and goals, the staff will evaluate the existing RIRIP activities to determine the extent to which they support these goals. From the results of this analysis, the staff can determine which RIRIP activities should continue, which activities should be sunset, and any new activities necessary to achieve the vision and goals. Table 1 provides a conceptual organization for the RIRIP planning template.

The new effectiveness review process would focus on determining whether completed RIRIP activities had achieved the desired outcomes and, if not, why not. In addition, the effectiveness review process would identify any needed corrective actions and lessons to be adopted as best practices for future activities. The staff will evaluate the assessment feedback mechanisms that are part of the NRC's Reactor Oversight Process and Operating Experience Program for

insights to develop the RIRIP effectiveness process.

Selected major milestones for the proposed RIRIP improvements are provided in Table 2. Figure 1 provides an overview of the proposed new RIRIP framework including the planning and effectiveness process. Specific elements are discussed below:

- **Evaluate current environment.** NRC Senior Management through the PRASC will evaluate the current environment and integrate Commission direction and stakeholder input through a strategic direction-setting function. This includes the initial development of the arena vision and goals and identification of risk-informed activities for the short and long term. As the environment evolves and using the results of the RIRIP effectiveness reviews, NRC Senior Management will modify and update the goals consistent with the established vision. NRC Senior Management will periodically interact with stakeholders on risk-informed initiatives.
- **Establish target environment.** The office division directors direct the implementation of risk-informed activities to achieve the RIRIP goals and set the overall risk-informed environment using office management tools and resources. Integration of activities across the NRC is facilitated through periodic interoffice meetings and establishment of standing committees, such as the NRC Risk Management Team (RMT) which addresses common risk-informed issues in the reactor safety arena. The RMT, which meets every 2 weeks, includes division-level participation from NRR and RES. The development of other division-level organizations similar to the RMT for the other arenas would improve oversight of regulatory activities.
- **Implement target environment.** The branch chiefs, through their staff, implement the program plans for risk-informed activities and set the overall risk-informed environment on a day-to-day basis.
- **Assess effectiveness.** The staff will propose to the PRASC a list of completed RIRIP that should be considered for the effectiveness review. The review would focus on assessing whether the activities had achieved their desired outcomes and on identifying improvements and best practices to be used for future risk-informed efforts.

TABLE 1— REPRESENTATIVE HIGH-LEVEL RIRIP PLANNING TEMPLATE

REACTOR ARENA—OPERATING REACTORS	
Risk-Informed Vision:	
Licensing Functional Area Goals (1–5 years) A. B. Activities to Achieve Goals 1. 2. 3.	Licensing Functional Area Goals (5–10 years) A. B. Activities to Achieve Goals 1. 2. 3.
Rulemaking Functional Area Goals (1–5 years) A. B. Activities to Achieve Goals 1. 2. 3.	Rulemaking Functional Area Goals (5–10 years) A. B. Activities to Achieve Goals 1. 2. 3.
Oversight Functional Area Goals (1–5 years) A. B. Activities to Achieve Goals 1. 2. 3.	Oversight Functional Area Goals (5–10 years) A. B. Activities to Achieve Goals 1. 2. 3.

Note: For each activity identified above, the staff would develop and maintain a detailed specific program plan as part of the RIRIP. Potentially, there would be no goals or supporting activities for some areas.

TABLE 2 — RIRIP IMPROVEMENT MILESTONES

Selected Major Milestones				
Milestone	Original Date	Revised Date	Completion Date	Lead Organization
Develop vision and functional area goals (submitted as part of semiannual RIRIP report)	April 2007			RES/NRR/NMSS/ NRO/FSME
Determine RIRIP activities necessary to meet goals	August 2007			RES/NRR/NMSS/ NRO/FSME
Communicate RIRIP vision, goals, and activities	October 2007			RES/NRR/NMSS/ NRO/FSME
Complete first effectiveness review	October 2008			RES/NRR/NMSS/ NRO/FSME

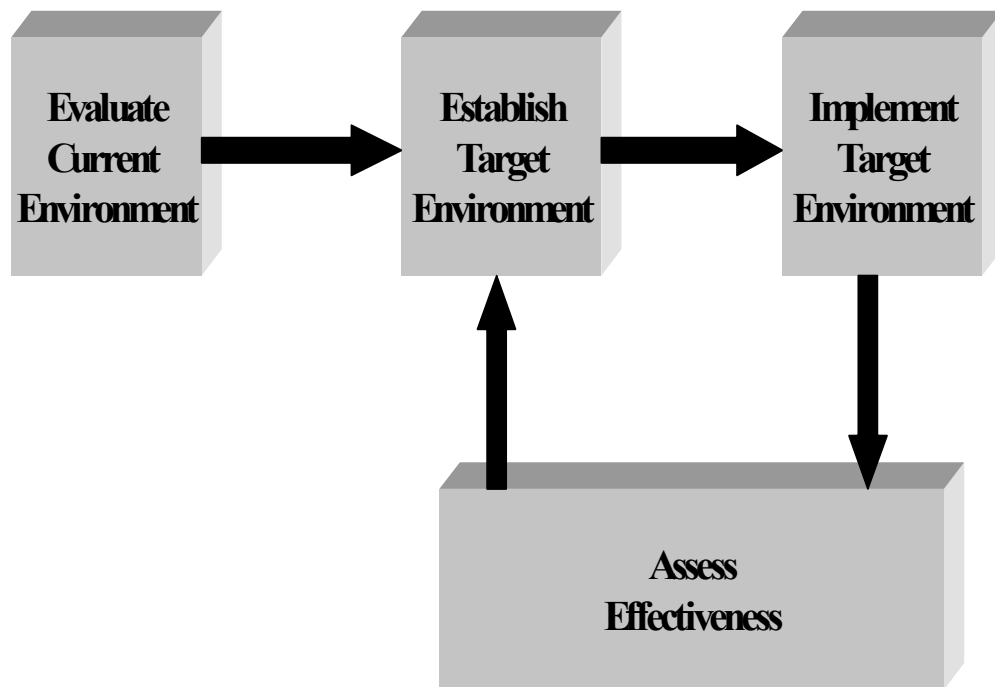


Figure 1 - New RIRIP Process Framework

HIGHLIGHTS OF MAJOR RISK-INFORMING ACTIVITIES

The following paragraphs highlight the major risk-informing activities that the staff has completed over the past 6 months and that are scheduled to be conducted over the next 6 months. This includes 12 of the activities in the risk-informed regulation implementation plan (RIRIP) (Enclosure 3)—5 related to “safety,” 6 related to “effectiveness,” and 1 related to “openness.”

SAFETY (Primary Fiscal Year (FY) 2004–2009 Strategic Plan Goal)

- 1. Industry Trends Support Program (SA-3):** The U.S. Nuclear Regulatory Commission’s (NRC’s) Industry Trends Program (ITP) monitors trends in indicators of industry performance to confirm that the safety of operating power reactors is being maintained. If any long-term indicators show statistically significant adverse trends, the NRC evaluates them and takes appropriate regulatory action using existing processes for resolving generic issues and issuing generic communications.

As part of ITP support, the Office of Nuclear Regulatory Research (RES) continued development of the baseline risk index for initiating events (BRIIE), an industrywide risk-informed performance indicator for initiating events. RES will address stakeholder comments on a draft report and will work with the Office of Nuclear Reactor Regulation (NRR) to finalize the methodology and details of implementation, including addressing differences between the BRIIE calculations and the comparable mitigating systems performance index (MSPI) methodology being developed to support the Reactor Oversight Process (ROP). The goal is to present BRIIE results and thresholds in the FY 2006 ITP paper (to be used in early calendar year (CY) 2007) and to incorporate BRIIE into the ITP and formally use BRIIE results as an ITP indicator in the FY 2007 ITP paper (to be issued in early CY 2008).

- 2. Accident Sequence Precursor (ASP) Program (SA-5):** The ASP Program evaluates risk associated with operational events and/or degraded conditions by systematically reviewing and evaluating operating experience to identify precursors to potential severe core damage sequences, documenting precursors, categorizing them by plant-specific and generic implications, and providing a measure of trends in nuclear plant core damage risk. The objectives of the ASP Program are to determine the safety significance of events and their regulatory implications; provide feedback to improve probabilistic risk assessment (PRA) models; and provide NRC Strategic Plan performance measures and the ASP occurrence rate trends for the NRC’s annual Performance and Accountability Report to Congress. Since its inception, the ASP Program has evaluated more than 650 precursors, which are maintained in the ASP events database.

In November 2006, RES will provide results on the number of significant precursors in FY 2005 to the ITP and the annual Performance and Accountability Report to Congress. By April 2007, RES will provide a preliminary assessment of FY 2006 events to support the Agency Action Review Meeting.

3. Risk Management of Technical Specifications (RMTS) (SA-10): The staff continues to work on the RMTS initiatives to add a risk-informed component to the standard technical specifications (STS). The following summarizes the major planned activities in this area:

- Initiative 1, “Modified End States”: This initiative would allow (following a risk assessment) some equipment to be repaired during hot shutdown rather than cold shutdown. The Technical Specification Task Force (TSTF)-423 for boiling-water reactor (BWR) plants was made available via the Consolidated Line Item Improvement Process (CLIIP) on March 23, 2006. The safety evaluation report for the Babcock & Wilcox (B&W) topical report was noticed for comment in May 2006 and was approved in August 2006. The Babcock & Wilcox Owners Group is preparing TSTF-431 to implement the B&W topical report. The Westinghouse topical report was submitted in September 2005 and is under review.
- Initiative 4b, “Risk-Informed Completion Times”: The overall objective of this initiative is to modify the technical specification (TS) to reflect a configuration risk management approach that is more consistent with the approach of the maintenance rule in Title 10, Section 50.65(a)(4), of the *Code of Federal Regulations* (10 CFR 50.65(a)(4)). The proposal involves a combination of the current TS completion times (CTs), a quantified risk assessment based on 10 CFR 50.65(a)(4) to determine CT extension feasibility, and CT backstop limits. The CT backstop limits ensure that low-risk safety functions are not permitted to be inoperable for an indefinite period of time. Industry submitted a risk management guidance document in August 2006. The South Texas Project and Fort Calhoun Station (Combustion Engineering (CE)) pilot plants are to be approved in FY 2007.
- Initiative 5b, “Surveillance Frequency Control Program”: The goal of this initiative is to develop a risk-informed process that would establish surveillance intervals based on risk insights, equipment availability and reliability factors, performance history, etc., to determine an “optimum” surveillance requirement frequency. Upon development and approval of this process, the intent is to retain the existing surveillance requirements in the technical specifications but to remove the equipment-specific surveillance test intervals to a licensee-controlled document. Industry submitted a revised process/methodology document in July 2006. The process/methodology document and Limerick pilot plant were approved in September 2006.
- Initiative 6, “Modification of Limiting Condition for Operation (LCO) 3.0.3, ‘Actions and Completion Times’”: The CE TSTF-426 safety evaluation was published in the *Federal Register*, with a request for public comment, as part of the CLIIP on July 20, 2006. The CE TSTF-426 is scheduled to become available for adoption via CLIIP in January 2007.
- Initiative 7, “Non-TS Support System Impact in TS System Operability”: This initiative would permit a risk-informed delay time before entering LCO actions for inoperability attributable to a loss of support function provided by equipment

outside of technical specifications. For example, TSTF-427 addresses hazard barrier inoperability. The safety evaluation for TSTF-427 was noticed for comment on June 2, 2006, and became available via CLIP in September 2006.

4. **Fire Protection for Nuclear Power Plants (SA-11):** The staff completed the rulemaking to endorse an alternative performance-based and risk-informed fire protection rule for operating nuclear power plants. The staff worked with the National Fire Protection Association (NFPA) to develop NFPA Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," 2001 Edition. The final rule to incorporate NFPA Standard 805, 2001 Edition, into 10 CFR 50.48c) appeared in the *Federal Register* in June 2004 and became effective on July 16, 2004. The Nuclear Energy Institute (NEI) developed an implementation guide, NEI 04-02, Revision 1, "Guidance for Implementing a Risk-Informed, Performance-Based Fire Protection Program Under 10 CFR 50.48c)." In May 2006, the NRC issued Regulatory Guide 1.205, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants." This regulatory guide endorsed NEI-04-02. To date, 40 operating nuclear power plants have indicated a desire to adopt this alternative rule.
5. **Assessing Performance of Steam Generator Tubes and Other Reactor Coolant System (RCS) Components During Severe Accidents (SA-18):** The staff has developed an improved PRA model for use in determining the frequency of pressurized-water reactor (PWR) containment bypass events that result from steam generator tube (SGT) failures induced by severe accident conditions. This work utilizes PRA, thermal-hydraulic analyses, and analyses of SGT and non-SGT RCS components. The staff has developed a prototype risk-informed model and has used this model to perform a preliminary evaluation of a sample Westinghouse 4-loop plant to calculate the frequency of severe accident containment bypass events attributable to SGT failures at that plant. The staff is currently evaluating the prototype model and the results of its application to the sample plant to determine the expansions and improvements needed in the model. Based on the results of that evaluation, the staff will determine the scope and schedule for the remainder of this project.

EFFECTIVENESS (Primary FY 2004–2009 Strategic Plan Goal)

1. **Develop PRA Standards and Related Guidance with National Standards Committees and Industry Organizations (EF-2):** The increased use of PRAs in the NRC's regulatory decisionmaking process requires consistency in the quality, scope, methodology, and data used in such analyses. To achieve this objective, professional societies, industry, and the staff have undertaken initiatives to establish consensus standards and guidance on the use of PRA in regulatory decisionmaking. Based on updates to the standards and guidance documents issued by the American Society of Mechanical Engineers and the NEI, the staff is revising Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of PRA Results for Risk-Informed Activities," and will issue Revision 1 for public review and comment in December 2006. Future revisions of Regulatory Guide 1.200 will address PRA quality standards for fire,

external events, and low power and shutdown operations risk assessments. The staff is also preparing a related guidance document, "Treatment of Uncertainties," and will issue a draft NUREG for public review and comment in December 2006.

2. **Develop Structure for Advanced Reactor Licensing (EF-6):** The staff developed a plan for a regulatory structure for advanced reactor licensing (i.e., non-light water reactors). In the plan, the staff proposed to create a new 10 CFR Part 53 which will constitute a new set of risk-informed requirements. In an SRM, dated March 22, 2006, the Commission approved the staff's plans. The staff issued the advance notice of proposed rulemaking in April 2006 and simultaneously placed the latest version of the technology-neutral framework on the RuleForum Web site. The staff will provide the Commission with a recommendation on whether to proceed with rulemaking in May 2007.
3. **Probabilistic Risk Assessment of Dry Cask Storage Systems (EF-14):** In support of the Commission's policies on risk-informing the regulatory process and performance goals, the staff is developing PRA methods and quantifying the risk associated with dry cask storage of spent nuclear fuel. This study is intended to provide (a) methods to quantify the risk of dry cask storage of spent nuclear fuel, (b) insights into decision-making on how to improve regulatory activities associated with 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," and (c) analytical tools that can be used to implement future waste safety goals and risk-informed regulatory activities. The staff presented the results of the final pilot PRA to the Advisory Committee on Nuclear Waste in July 2006..
4. **Reactor Oversight Process Support (EF-20):** RES supports the ROP by developing and piloting the MSPI and developing models and guidelines for the Risk Assessment Standardization Project (RASP).

The MSPI monitors risk associated with changes in performance of selected mitigating systems, while accounting for plant-specific design and performance data. Toward that end, the MSPI enhances the safety of nuclear plants by addressing known problems with the existing safety system unavailability performance indicator and providing a measure of both system reliability and availability.

In April 2006, RES provided to NRR data and guidance to help resolve issues concerning requirements for PRA quality to support MSPI implementation and provided input to the agency's document on these PRA requirements. RES also participated in staff review teams to review licensees' submittals of MSPI basis documents and provided input to the NRC's review findings and documents on the licensee submittals.

In June 2006, RES documented both the results of the technical analyses used to guide and focus MSPI reviews and the database used to support the technical analyses.

In July 2006, as part of RASP support, RES completed trial use of the guidelines and updated them (as needed) for the expert elicitation process to be used in plant operating event analysis. In addition, in September 2006, also as part of RASP support, RES

developed analysis guidelines for trial use for external events (internal fire, internal flooding, seismic, and high wind) during power operations.

5. **Standardized Plant Analysis Risk (SPAR) Model Development Program (EF-21):** RES is developing plant-specific PRA (known as SPAR models) that model accident sequence progression, plant systems and components, and plant operator actions. These models are easy-to-use tools that enable the NRC staff to perform risk-informed regulatory activities by independently assessing the risk of events or degraded conditions at operating nuclear power plants. SPAR models for internal initiating events during full-power operation are available for all 72 plant sites in the United States. The staff is currently developing models for internal initiating events during low-power and shutdown operations, for calculating large early release frequency, and for external initiating events (fires, floods, seismic events, high winds, etc.).

In April 2006, RES provided NRR and the regions with a semiannual progress report for enhanced Revision 3 SPAR model accomplishments (including cut-set level revisions for 24 additional models) as part of the RASP support.

The staff is currently using SPAR models to support the development of the state-of-the-art reactor consequence analysis of severe accidents at nuclear power plants. Based on insights resulting from this activity, the staff plans to update the SPAR models, as appropriate, based on current plant capabilities and safety enhancements. Initially, the plants to be evaluated will be the six lead (pilot) plants in the state-of-the-art reactor consequence analysis project. In addition, the staff will update the SPAR models, as appropriate and on a plant-by-plant basis, to include plant safety enhancements resulting from Phases 1, 2 and 3 Section B.5.b assessments as the engineering and risk information on the pertinent systems become available to the staff as part of normal NRC regulatory activities.

6. **Changes to Technical Requirements of 10 CFR 50.46 (EF-22):** The Commission's SRM on SECY-02-0057, dated March 31, 2003, approved most staff recommendations regarding possible changes to loss-of-coolant accident (LOCA) requirements and also directed the staff to prepare a proposed rule that would provide a risk-informed alternative maximum break size. The Commission subsequently provided additional direction in an SRM dated July 1, 2004. In response, the staff prepared a proposed rule containing emergency core cooling system (ECCS) evaluation requirements as an alternative to those specified in 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems (ECCS) for Light-Water Nuclear Power Reactors." These alternative requirements would be codified in a new regulation, 10 CFR 50.46a (the existing 10 CFR 50.46a would be redesignated as 10 CFR 50.46b), and could be used in lieu of the requirements in 10 CFR 50.46 by current nuclear power reactor licensees. The Commission issued the proposed rule for public comment in November 2005. The proposed rule affords licensees flexibility to establish quantitative acceptance criteria for maintenance of "coolable geometry" for breaks that are beyond the design basis, as specified in the new 10 CFR 50.46a.

Public workshops took place on February 16, June 28, and August 17, 2006, to discuss the language of the draft-final rule. The staff expects to deliver the draft final rule to the Commission by February 2007.

In support of 50.46 rulemaking, the staff conducted an expert elicitation process to improve its understanding of the LOCA frequency as a function of the break size. The expert elicitation process, discussed in draft NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process," provides preliminary LOCA frequency estimates developed using an expert elicitation process to consolidate service history data, insights from probabilistic fracture mechanics studies with the knowledge of plant design, operation, and material performance. The staff accepted public comments on NUREG-1829 through November 2005 and is now evaluating these comments to determine whether adjustments to the methodology are necessary. The draft-final version of the NUREG is expected by November 2006. The staff plans to discuss the report with the Advisory Committee on Reactor Safeguards in the fall of 2006 and, following that, plans to publish it by December 2006.

OPENNESS (Primary FY 2004–2009 Strategic Plan Goal)

1. **Improve PRA communication to stakeholders (OP-1):** Staff from the Offices of NRR, RES, and Public Affairs (OPA) are working together to develop a range of communication approaches to reach the agency's diverse body of stakeholders. The interoffice team expects to complete two activities in the next 6 months.

First, a redesign of the NRC public Web site is underway to make information on the purpose and use of PRA applications easier for the public to find and understand. This redesign will not only allow interested parties to access the latest information quickly, but it will also draw the attention of the casual Internet browser to the agency's risk-informed activities. Updates to the public Web site will replace Enclosure 3 of the next update of the RIRIP.

Second, the staff will rewrite fact sheets related to risk (currently "Probabilistic Risk Assessment" and "Nuclear Reactor Risk") to improve clarity and will update them to include the latest risk-informed initiatives. OPA commonly uses these fact sheets as reference material to respond to questions from the media and other stakeholders. The fact sheets are also available in a prominent location on the agency's public Web site ("Fact Sheets and Brochures" link from the main page), which makes them easily accessible.

Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
October 2006

TABLE OF CONTENTS

List of Abbreviations	v
Foreword	ix

RISK-INFORMED REGULATION IMPLEMENTATION PLAN

Background	Part 1-1
Organization	Part 1-2

PART 1. RISK-INFORMED REGULATION

1. Relevance to Strategic Plan	Part 1-3
2. Guidelines for Candidate Requirements, Practices, and Processes ..	Part 1-3
3. Factors To Consider in Risk-Informed Regulation	Part 1-4
Defense-in-Depth	Part 1-5
Safety Margins	Part 1-7
The ALARA Principle	Part 1-8
Safety Goals	Part 1-9
Performance-Based Implementation	Part 1-9
Voluntary Alternatives Versus Mandatory Requirements	Part 1-9
Selective Implementation	Part 1-10
Regulatory Oversight Activities	Part 1-10
Regulatory Analysis	Part 1-10
4. Communication Plans	Part 1-11
5. Training Program	Part 1-11

PART 2. RISK-INFORMED REGULATION IMPLEMENTATION ACTIVITIES

Introduction to Part 2	Introduction-1
------------------------------	----------------

CHAPTER 1. SAFETY

Goal: Ensure Protection of Public Health and Safety and the Environment

1.1.	Introduction	Chap. 1-1
1.2	Safety Strategies	Chap. 1-4
1.3	Current “Safety” Initiatives and Activities	Chap. 1-4
SA-1	Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information	Chap. 1-6
SA-2	Reactor Oversight Process (ROP) support (renamed EF-20)	
SA-3	Industry Trends Program support	Chap. 1-9
SA-4	Reactor Performance Data Collection Program	Chap. 1-11
SA-5	Accident Sequence Precursor (ASP) Program	Chap. 1-14
SA-6	SPAR Model Development Program (renamed EF-21)	
SA-7	Incorporate risk information into the high-level waste regulatory framework	Chap. 1-16
SA-8	Change technical requirements of 10 CFR 50.46 (renamed EF-22)	
SA-9	Digital systems probabilistic risk assessment (PRA)	Chap. 1-19
SA-10	Develop risk-informed improvements to standard technical specifications	Chap. 1-22
SA-11	Fire protection for nuclear power plants	Chap. 1-25
SA-12	Incorporate risk information into the decommissioning regulatory framework	Chap. 1-27
SA-13	Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking	Chap. 1-29
SA-14	Evaluation of loss-of-offsite-power events and station blackout risk	(completed)
SA-15	Exemptions from licensing and distribution of byproduct material: licensing and reporting requirements	Chap. 1-32
SA-16	Materials licensing guidance consolidation and revision	Chap.1-34
SA-17	Implementation of Part 70 revision	Chap.1-36
SA-18	Assessing performance of steam generator tubes and other reactor coolant system (RCS) components during severe accidents (formerly EF-5)	Chap.1-39
SA-19	Risk-Informing the Standard Review Plan (SRP) - Improving New Reactor Review Efficiency Through Application of Risk Insights	Chap.1-41

CHAPTER 2. EFFECTIVENESS

Goal: Ensure That NRC Actions Are Effective, Efficient, Realistic, and Timely

2.1.	Introduction	Chap. 2-1
2.2	Effectiveness Strategies	Chap. 2-2
2.3.	Current Effectiveness Initiatives and Activities	Chap. 2-3
EF-1	Creating a risk-informed environment	Chap. 2-5
EF-2	Develop standards and related guidance for appropriate PRA quality and the application of risk-informed, performance-based regulation in conjunction with national standards committees and industry organizations	Chap. 2-7
EF-3	Develop and maintain analytical tools for staff risk applications	Chap. 2-11
EF-4	Develop the technical basis to revise the PTS rule	Chap. 2-12
EF-5	Develop methods for assessing steam generator performance during severe accidents (renamed SA-18)	
EF-6	Develop structure for new plant licensing (advanced reactor framework)	Chap. 2-14
EF-7	Develop and apply methods for assessing fire safety in nuclear facilities	Chap. 2-17
EF-8	Coherence program	Chap. 2-20
EF-9	Establish guidance for risk-informed regulation: development of human reliability analysis	Chap. 2-21
EF-10	PRA review of advanced reactor applications	Chap. 2-24
EF-11	Developing a framework for incorporating risk information in the NMSS regulatory process	Chap. 2-26
EF-12	Develop risk guidelines for the materials and waste arenas	(completed)
EF-13	Systematic decisionmaking process development	(completed)
EF-14	Probabilistic risk assessment of dry cask storage systems	Chap. 2-28
EF-15	Interagency Jurisdictional Working Group evaluation of the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium and/or thorium	Chap. 2-30
EF-16	Multiphase review of the byproduct materials program (implementation of Phase I and Phase II recommendations)	(completed)
EF-17	Revise Part 36: Requirements for Panoramic Irradiators (PRM-36-01)	Chap. 2-32

EF-18	Develop an alternative risk-informed approach to special treatment requirements in Part 50 to vary the treatment applied to structures, systems, and components (SSC) on the basis of their safety significance using a risk-informed categorization method	Chap. 2-34
EF-19	Develop a plan for making a risk-informed, performance-based revision to 10 CFR 50 (Part 50)	(completed)
EF-20	Reactor Oversight Process (ROP) support (formerly SA-2)	Chap. 2-37
EF-21	SPAR Model Development Program	Chap. 2-40
EF-22	Change technical requirements of 10 CFR 50.46 (formerly SA-8)	Chap. 2-43
EF-23	Risk-informing of Standard Review Plans For Independent Spent Fuel Storage Installations and Packages	Chap. 2-47

CHAPTER 3. OPENNESS

Goal: Ensure Openness in Our Regulatory Process

3.1.	Introduction	Chap. 3-1
3.2	Openness Strategies	Chap. 3-2
3.3.	Current Openness Initiatives and Activities	Chap. 3-2
OP-1	Improve PRA communication to stakeholders	Chap. 3-3

LIST OF ABBREVIATIONS

ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee for Reactor Safeguards
ALARA	as low as reasonably achievable
AECL	Atomic Energy of Canada, Ltd.
ANPR	advance notification of proposed rulemaking
ANS	American Nuclear Society
AOT	allowable/allowed outage time
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
ATHEANA	A Technique for Human Event Analysis
ATWS	anticipated transient without SCRAM
BWR	boiling-water reactor
BWROG	Boiling Water Reactor Owners Group
CANDU	Canadian Deuterium-Natural Uranium Reactor
CCF	common-cause failure
CDF	core damage frequency
CFR	<i>U.S. Code of Federal Regulations</i>
CLIP	Consolidated Line Item Improvement Process
CNSI	Chem-Nuclear Systems, Inc.
CRCPD	Conference of Radiation Control Program Directors
CRGR	Committee To Review Generic Requirements
CRMP	configuration risk management program
CSNI	Committee on the Safety of Nuclear Installations
DG	diesel generator
	draft guide
DOE	Department of Energy
DPO	differing professional opinion
DSI	direction-setting issue
ECCS	emergency core cooling system
EPA	Environmental Protection Agency
EPIX	equipment performance and information exchange
EPRI	Electric Power Research Institute
ESBWR	(GE) economic simplified boiling water reactor
ET	Executive Team
FAVOR	a probabilistic fracture mechanics code
FCSS	Division of Fuel Cycle Safety and Safeguards (NMSS/FCSS)
FSAR	final safety analysis report

FTE	full-time employee/employees
GAO	General Accounting Office (now Government Accountability Office)
GDC	general design criterion/criteria
GE	General Electric Company
GEM	Graphical Evaluation Module
GL	generic letter
GQA	graded quality assurance
GSI	generic safety issue
HERA	Human Event Repository and Analysis
HRA	human reliability analysis
HLW	high-level waste
IDCCS	Integrated Data Collection and Coding System
IMC	Inspection Manual chapter
IMNS	Division of Industrial and Medical Nuclear Safety (NMSS/IMNS)
INPO	Institute of Nuclear Power Operations
IPEEE	individual plant examination for external events
IPE	individual plant examination
ISFSI	independent spent fuel storage installation
ISA	integrated safety analysis
ISI	inservice inspection
IST	inservice testing
LCO	limiting conditions for operation
LER	licensee event report
LERF	large early release frequency
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
LP/SD	low-power/shutdown
LRS	low-risk-significant
LT	Leadership Team
LTR	license termination rule
LWR	light-water reactor
MACCS	MELCOR accident consequence code system
MOR	monthly operating report
MSLB	main steam line break
MSPI	Mitigating Systems Performance Index
NEI	Nuclear Energy Institute
NFPA	National Fire Protection Association
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NOED	notice of enforcement discretion
NRC	Nuclear Regulatory Commission
NRS	non-risk-significant

NRR	NRC Office of Nuclear Reactor Regulation
OAS	Organization of Agreement States
OCFO	NRC Office of the Chief Financial Officer
OEDO	NRC Office of the Executive Director for Operations
OM	operation and maintenance
OSTP	NRC Office of State and Tribal Programs
PA	performance assessment
PBPM	planning, budgeting, and performance management
PRA	probabilistic risk assessment
PRASC	PRA Steering Committee
PRM	petition for rulemaking
PTS	pressurized thermal shock
PWR	pressurized-water reactor
QA	quality assurance
RADS	Reliability and Availability Data System
RASP	Risk Assessment Standardization Project
RBI	risk-based performance indicators
RCS	reactor coolant system
RES	NRC Office of Nuclear Regulatory Research
RG	regulatory guide
RI	risk-informed
RIE	risk-informed environment
RILP	risk-informed licensing panel
RIPB	risk-informed, performance-based
RIRIP	Risk-Informed Regulation Implementation Plan
RIS	regulatory issue summary
ROP	Reactor Oversight Process
RPV	reactor pressure vessel
RTG	Risk Task Group (NMSS)
SAPHIRE	Systems Analysis Program for Hands-on Integrated Reliability Evaluation
SBO	station blackout
SCRAM	rapid (emergency) shutdown of a nuclear reactor
SCSS	sequence coding and search system
SDP	Significance Determination Process
SFPO	Spent Fuel Project Office (NMSS)
SG	steam generator
SGTAP	Steam Generator Task Action Plan
SNM	special nuclear material
SPAR	standardized plant analysis risk
SRM	staff requirements memorandum
SRP	standard review plan
STP	South Texas Project

STS	standard technical specifications
SSC	structures, systems, and components
TBD	to be determined
TI	temporary instruction
TMI	Three Mile Island
TS	technical specification
TSTF	Technical Specification Task Force
TTC	NRC Technical Training Center
TXS	(Siemens) Teleperm XS
UAI	(system) unavailability index
URI	(system) unreliability index
USI	unresolved safety issue
WOG	Westinghouse Owners Group

FOREWORD

The NRC has for many years developed and adapted methods for doing probabilistic risk assessments (PRAs) and performance assessments (PAs) to better understand risks from licensed activities. The NRC has supported development of the science, the calculation tools, the experimental results, and the guidance necessary and sufficient to provide a basis for risk-informed regulation. By the mid-1990s, the NRC had a sufficient basis to support a broad range of regulatory activities. The Commission's 1995 PRA policy statement provides guidance on risk-informing regulatory activities. In this policy statement, the Commission said 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." This plan implements that policy.

In the policy statement, the Commission said it expected implementation of the policy statement to improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees. The movement toward risk-informed regulation has indeed sharpened the agency's (and, therefore, the licensees') focus on safety, reduced unnecessary regulatory burden, and fostered an effective, efficient regulatory process. A collateral benefit is the opportunity to update the technical bases of the regulations to reflect advances in knowledge and methods and decades of operating experience. In line with the NRC's goal of ensuring openness in our regulatory process, the agency is considering risk-informed regulation with a view to giving the public and the nuclear industry clear and accurate information and a meaningful role in the process.

In 1998 the agency formally defined risk-informed regulation as an approach to regulatory decisionmaking that uses risk insights as well as traditional considerations to focus regulatory and licensee attention on design and operational issues commensurate with their importance to health and safety. A risk-informed approach enhances the traditional approach by (a) explicitly considering a broader range of safety challenges; (b) prioritizing these challenges on the basis of risk significance, operating experience, and/or engineering judgement; (c) considering a broader range of countermeasures against these challenges; (d) explicitly identifying and quantifying uncertainties in analyses; and (e) testing the sensitivity of the results to key assumptions. A risk-informed regulatory approach can also be used to identify insufficient conservatism and provide a basis for additional requirements or regulatory actions.

RISK-INFORMED REGULATION IMPLEMENTATION PLAN

Background

The Nuclear Regulatory Commission's (NRC's) policy for implementing risk-informed regulation was expressed in the 1995 policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities (*Federal Register*, 60 FR 42622, August 16, 1995):

(1) 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.

(2) 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.

(3) PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

(4) 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.

The Commission also indicated that because of the differences in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that more than one approach is required for incorporating risk analyses into the regulatory process. However, PRA methods and insights will be broadly applied to ensure that the NRC makes best use of available techniques to foster consistency in incorporating risk analysis, risk assessment, and risk information into its decisionmaking.

In issuing the policy statement, the Commission said it expected that implementation of the policy statement would improve the regulatory process by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees.

In the March 1999 report "Nuclear Regulation - Strategy Needed to Regulate Safety Using Information on Risk" (GAO/RCED-99-95), the General Accounting Office made the following recommendation:

To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the staff to develop a comprehensive strategy that includes but is not limited to objectives, goals, activities, and time frames for risk-informed regulation; specifies how the Commission expects to define the scope and implementation of risk-informed regulation; and identifies the manner in which it expects to continue the free exchange of operational information necessary to improve the quality and reliability of risk assessments.

In a January 2000 memorandum to the Commission, the staff outlined a strategy for risk-informed regulation. In March 2000, the staff gave the Commission an initial version of the Risk-Informed Regulation Implementation Plan (RIRIP). The Commission reviewed the plan and, after a March briefing by the staff, directed the staff, in April 2000, to include in the next update of the implementation plan an internal communications plan, training requirements for the staff, and a discussion of internal and external factors that may impede risk-informed regulation. The October 2000 version of the implementation plan was the first complete version. The purpose of the plan was to integrate the Commission's risk-informing activities and include the supplementary material the Commission asked for in April 2000.

The Commission was briefed by the NRC staff on the RIRIP on November 17, 2000. Subsequently, on January 4, 2001, the Commission requested that the staff more clearly indicate the priorities of the activities; provide a more detailed communication plan; identify resources and tools needed; address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations; and identify the items that are on the critical path and have crosscutting dimensions.

On May 3, 2006, the staff briefed the Commission on the status of risk-informed and performance-based reactor regulation. In a staff requirements memorandum dated June 1, 2006, the Commission directed the staff to improve RIRIP so that it is an integrated master plan for activities designed to help the agency achieve the Commission's goal of a holistic, risk-informed and performance-based regulatory structure. The Commission indicated that RIRIP should continue to give priority to risk-informed activities underway and incorporate lessons learned from earlier activities as appropriate.

This is the latest update of the RIRIP, developed in accordance with the SRMs dated January 4, 2001 and June 1, 2006.

Organization of the RIRIP

The RIRIP has two parts. Part 1 is a general discussion of risk-informed regulation: the relevance of the RIRIP to the agency's strategic plan; general guidelines for identifying candidate requirements, practices, and processes that may be amenable to, and benefit from, an increased use of risk insights; factors to consider in risk-informing the agency's activities (including defense-in-depth, safety margins, the ALARA principle, and safety goals), and communications plans and training programs.

Part 2 of the plan describes the staff's activities for risk-informed regulation that are specific to the strategic goals. Part 2 is based on the Commission's strategic plan for FY 2004-2009. There is a chapter on the safety strategic plan goal, a chapter on the effectiveness strategic plan goal, and a chapter on the openness strategic plan goal. Each chapter is organized around the current strategic plan strategies relevant to risk-informed regulation in that area. The implementation activities for each strategy are described, significant milestones are listed, and milestones schedules are noted. Progress in completing established milestones is also discussed.

Implementation activities supporting safety or effectiveness goals may substantially differ in scope, form, and content because the nature of the activities being regulated varies greatly, as does the availability of risk assessment methods. This plan condenses detailed descriptions of staff activities in various Commission papers, program plans, and office operating plans.

PART 1: RISK-INFORMED REGULATION

1. Relevance to the Strategic Plan

While the PRA policy statement and other risk-informed regulatory initiatives were being developed, the NRC also developed a strategic plan for accomplishing its mission. In August 2004, the agency issued a revised strategic plan for fiscal years 2004 to 2009 (FY 04-09). This new plan established five goals, and the associated strategies which the NRC will use to achieve each goal. The goals are safety, security, openness, effectiveness, and management.

In response to the release of the strategic plan for FY 04-09, the staff revised the RIRIP to make it consistent with the five goals in the FY 04-09 strategic plan. In this RIRIP update, each activity lists the primary and secondary strategic plan goals and strategies associated with the FY 04-09 plan. In particular, each activity listed has safety, effectiveness, and openness as its primary FY 04-09 strategic plan goal.

The strategic plan provides guidance for the agency's initiatives to support risk-informed regulation by defining strategic goals and outcomes and the strategies and means for each goal. The RIRIP specifies ongoing or planned activities to implement strategic plan strategies for risk-informed regulation and includes:

- draft criteria for risk-informing a program, practice, or requirement
- factors to consider in risk-informing a program, practice, or requirement
- relevance to performance-based regulation

The purpose of this plan is to integrate the Commission's risk-informing activities by identifying requirements and practices to be risk-informed and the necessary data, methods, guidance, and training. This plan is also intended to explain the agency's risk-informed regulatory policy to the public and the nuclear industry. The challenge in developing the RIRIP was to specify staff activities that are both necessary and sufficient to implement the strategic plan strategies. To show the relevance of the RIRIP to the strategic plan, the implementation activities and milestones in Part 2 of the RIRIP are described as implementing risk-informed regulatory strategies of the strategic plan.

2. Guidelines for Candidate Requirements, Practices, and Processes

As the Federal agency responsible for regulating the civilian applications of nuclear technology, the NRC licenses a wide range of activities, including nuclear power generation, nuclear materials disposal, transportation and storage, nuclear materials processing and fabrication, and industrial and medical applications. The staff has developed screening considerations for identifying regulatory activities that could benefit from risk information. The draft screening criteria were originally published in *Federal Register* notices (65 FR 14323, 03/16/00, and 65 FR 54323, 09/07/00). The staff finalized the criteria as considerations after reviewing comments received at workshops and public meetings and the staff's experience in applying the criteria. The final screening considerations are as follows:

- (1) Could a risk-informed regulatory approach help address one or more goals in the agency's strategic plan?

If the answer to consideration 1 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

- (2) Are current analytical models and data of sufficient quality, or could they be reasonably developed, to support risk-informing a regulatory activity?

If the answer to consideration 2 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

- (3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, the applicant, the licensee, and/or the public, and provide a net benefit?

If the answer to consideration 3 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

- (4) Do other factors exist that would limit the utility of implementing a risk-informed approach?

If the answer to consideration 4 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or screened out.

3. Factors To Consider in Risk-Informed Regulation

The NRC mission is to “license and regulate the Nation’s civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.” Historically, the agency has used an effective, albeit often conservative, approach for regulatory decisions. To accomplish its mission, the agency has established a regulatory system which presumes that the public health and safety are adequately protected when licensees comply with regulations and license requirements. Regulations justified on the basis of adequate protection do not consider cost because they are required for safety.

Since adequate protection is presumptively provided by existing regulations, the Commission has determined that, for nuclear power plants and fuel cycle facilities, proposed safety improvements beyond adequate protection should be adopted only if they provide “substantial” additional protection and if the direct and indirect costs are justified. In the area of nuclear reactor safety, regulatory analysis guidelines and backfit analysis guidelines have been developed for assessing a “substantial” improvement and calculating cost-benefit. In the area of materials safety the Commission has directed the staff to develop similar guidelines for fuel cycle facilities.

Risk-informed requirements must maintain reasonable assurance of adequate protection. A challenge in risk-informed regulation will be to maintain an acceptable level of safety while improving effectiveness, efficiency, and realism in agency decisions, practices, and processes and ensuring openness in the agency’s regulatory process.

The following factors should be considered in risk-informing an agency requirement or practice:

- Defense-in-depth
- Safety margins
- As low as reasonably achievable (ALARA) principle
- Safety goals
- Performance-based implementation
- Voluntary alternatives versus mandatory requirements
- Selective implementation
- Regulatory oversight activities
- Regulatory analysis

Since risk information is to be used to complement the traditional deterministic approach, risk-informed activities must preserve certain key principles of the deterministic approach. Among these principles are the fundamental safety principles of defense-in-depth and safety margins, the principle of ALARA radiation protection, and the agency's safety goals. The NRC has used these principles in its regulatory programs to maintain acceptable risk levels, and ensure that the civilian use of nuclear material is safe. In risk-informing its requirements and practices, the NRC must use these principles to complement risk information in ensuring that regulations focus on the issues important to safety and account for uncertainties affecting regulatory decisions.

Defense-in-Depth

Defense-in-depth is the use of successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is a philosophy used by the NRC to provide redundancy for facilities with "active" safety systems. This multiple-barrier approach is also used to protect against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

The principle of defense-in-depth has always been and will continue to be fundamental to regulatory practice in the nuclear field. It is expected that defense-in-depth for reactors and nuclear materials (which includes disposal, transportation and storage, processing and fabrication, and industrial and medical applications) may need to be considered differently due to the greater diversity in licensed materials activities and to the differences in safety issues.

In its May 25, 2000, letter to Chairman Meserve, the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) provided a perspective on the role of defense-in-depth in risk-informed regulation.

The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:

- Defense-in-depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and

extent of compensatory measures should be related, in part, to the degree of uncertainty.

- The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity.
- How good each compensatory measure should be is, to a large extent, a value judgement and, thus, a matter of policy.

The ACRS/ACNW letter further stated that defense-in-depth entailed “placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis reactor accidents that represent the range of important accident sequences.” Regulatory Guide (RG) 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

- a reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and consequence mitigation,
- programmatic activities are not overly relied on to compensate for weaknesses in equipment or devices,
- system redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., there are no risk outliers),
- the independence of barriers is not degraded, defenses against potential common-cause failures of multiple barriers are preserved, and the potential for the introduction of new common-cause failure mechanisms is assessed,
- defenses against human errors are preserved, and
- the intent of the fundamental design features is maintained.

ACRS has expressed concerns about the role of defense-in-depth in a risk-informed regulatory scheme. The Committee cites instances in which “seemingly arbitrary appeals to defense-in-depth have been used to avoid making changes in regulations or regulatory practices that seemed appropriate in the light of results of quantitative risk analyses.” The letter’s attachment describes the scope and nature of defense-in-depth in two models. “In the structuralist model, defense-in-depth is primary, with PRA available to measure how well it has been achieved.” (This is the model implicit in the agency’s PRA policy statement and in RG 1.174 concerning risk-informed changes to reactor licensing bases.) In the rationalist model, “the purpose of defense-in-depth is to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved. What distinguishes the rationalist model from the structural model is the degree to which it depends on establishing quantitative acceptance criteria, and then carrying formal analyses, including analysis of uncertainties, as far as the analytical methodology permits.”

To define the role of defense-in-depth in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- What elements of defense-in-depth should be independent of risk information?
 - measures to provide prevention and mitigation protection?
 - use of good engineering practices (e.g., codes and standards)?
 - number and nature of barriers to radiation release?

- emergency plans and procedures?
- What elements of defense-in-depth should be dependent upon risk information?
 - the balance between prevention and mitigation?
 - the number of barriers?
 - the need for redundancy, diversity, and independence of systems?
 - the events that need to be considered in the design?
- Do the defense-in-depth considerations in RG 1.174 apply?

Risk insights can make the elements of defense-in-depth clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

In implementing risk-informed changes to requirements or practices, the staff should ask:

- Is defense-in-depth commensurate with the risk and uncertainty associated with the estimate of risk?
- Is a reasonable balance preserved among accident prevention, radiation exposure prevention, and consequence mitigation?
- Are programmatic activities overly relied on to compensate for design weaknesses?
- Are redundancy, independence, and diversity of the system commensurate with the expected frequency and consequences of challenges to the system and with the uncertainties?
- Are defenses against potential common-cause failures preserved and have potential new common-cause failure mechanisms been assessed?
- Is the independence of barriers preserved?
- Are defenses against human errors preserved?

Safety Margins

Existing regulations were developed to ensure adequate safety margins to account for uncertainties in analyses and data and to ensure that adequate time is available to prevent the consequences of events. Safety margins are part of defense-in-depth; they assure safety in spite of uncertainties.

Regulatory Guide 1.174 states that acceptable risk-informed changes to a nuclear power reactor's licensing basis will be consistent with the principle that sufficient safety margins are maintained. Improved information from data analysis, research experiments, and the like suggest that some safety margins are excessive, given the current state of knowledge and current uncertainties. As regulations are evaluated to improve the focus on safety, regulations that require excessive safety margins will be candidates for change. To define the role that safety margins play in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- How should safety margins be employed to account for uncertainties in engineering analysis?

- best estimate analysis with conservative acceptance criteria?
 - specified confidence level?
 - role of codes and standards (i.e., do they inherently address safety margins)?
- How should safety margins be employed to account for uncertainty in risk?
 - parameter uncertainty; defense-in-depth (i.e., redundancy, diversity, independence)?
 - incompleteness in risk analysis (e.g., engineering judgement)?
 - model uncertainty (e.g., conservative acceptance criteria)?

In making risk-informed changes to requirements or practices, the staff should ask:

- What safety margins are acceptable given the risk significance of the regulated activity and uncertainties?
- Is the proposed change consistent with the principle that sufficient and realistic safety margins be maintained?
- Is there a method for evaluating whether safety margins will be adequately maintained?

The ALARA Principle

Consistent with the linear hypothesis of radiation protection, licensees are expected to keep radiation releases as low as reasonably achievable (ALARA). Conservatism introduced by applying the ALARA principle compensates for uncertainties about the precise point at which no adverse health effects occur.

The 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR) contended that, in the absence of better data, there was no reasonable alternative to the linear hypothesis of radiation protection. The linear hypothesis assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur. Indeed, the linear hypothesis may overestimate the risks by failing to account for the effects of dose rate and cell repair. The 1990 BEIR-V report reaffirmed that the linear, no-threshold model risk of cancer (other than leukemia) was most consistent with the data. Consequently, licensees are expected to keep radiation releases as low as reasonably achievable. In keeping with the ALARA principle, the staff seeks to strike a balance that considers the capabilities of technology and the costs of equipment while providing ample protection to the public. That is, the staff takes into account “the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.”

In making risk-informed changes to requirements or practices, the staff should ask:

- Is the risk-informed change consistent with the ALARA principle?
- If the ALARA principle is not used, how are limits set?

Safety Goals

In general, a safety goal is useful to define the desired level of safety. For nuclear power reactors, safety goals were originally established to define “how safe is safe enough” or, in other words, when additional regulation is not warranted. The agency uses these goals as benchmarks for calculated risk measures. The Commission has directed the staff to develop risk guidelines for other civilian uses of nuclear material, while taking the diversity of the applications into account.

In risk-informing requirements or practices, the staff should ask:

- Does the practice provide a level of safety commensurate with applicable safety goals?

Performance-Based Implementation

The agency has defined a performance-based requirement as one that has a measurable (or calculable) outcome (the licensee must meet the performance) while giving the licensee flexibility in meeting these outcomes. NUREG/BR-0303, “Guidance for Performance-Based Regulation,” provides guidance to staff working on regulations incorporating performance-based approaches to a wide range of regulatory issues. The report is intended to promote the use of a performance-based regulatory framework throughout the agency. NUREG/BR-0303 incorporates the high-level guidelines into internal NRC activities and applies the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decisionmaking and allows licensee flexibility in meeting a regulatory requirement. This in turn can result in a more efficient and effective regulatory process.

To the extent appropriate, staff activities to risk-inform regulations should also incorporate the performance-based approach to regulation. The corollary is also true that performance-based regulations should be risk-informed when possible.

In assessing performance-based implementation of risk-informed regulations, the staff should ask:

- Are there measurable or calculable parameters and criteria for judging the licensee’s or the system’s performance?
- Do the parameters and criteria provide opportunities to take corrective action if performance is deficient?
- Can the risk-informed change be made as a performance-based change?
- Is there flexibility for NRC and licensees consistent with an acceptable level of safety margin?

Voluntary Alternatives Versus Mandatory Requirements

The Commission has promulgated several regulations which permit reactor licensees to voluntarily implement risk-informed requirements or continue to operate under current requirements. The decision whether to give licensees this choice is determined by the backfit rule and safety considerations. In risk-informing the agency’s regulations, the staff may identify areas where mandatory requirements are warranted. The staff will evaluate proposed new requirements in line with existing guidance.

When considering voluntary versus mandatory implementation of risk-informed regulation, the staff should ask:

- Should all applicable licensees be required to implement the revised, risk-informed regulation? If so, have the criteria of 10 CFR 50.109, the backfit rule, been met?
- Should the regulation offer licensees alternative requirements?
- If staff practices are risk-informed, are they mandatory or voluntary?

Selective Implementation

The issue is whether licensees that wish to use risk-informed options may selectively implement the risk-informed option or must implement the risk-informed option in its entirety. Although the staff has recommended, and the Commission has concurred, that licensees not be allowed to select which specific requirements within a risk-informed rule to follow, selective implementation is decided on a case-by-case basis for other risk-informed initiatives.

In weighing selective implementation of risk-informed changes to requirements or practices, the staff should ask:

- Are there acceptable methods for assessing the effect of selective implementation on safety?
- Would selective implementation decrease the agency's efficiency and effectiveness?
- In general, what limits, if any, should be placed on selective implementation?

Regulatory Oversight Activities

The agency's regulatory oversight activities consist of inspection, use of performance indicators, assessment, and enforcement. The staff should consider the implications of risk-informed regulatory changes on regulatory oversight activities and ask about every risk-informed regulation:

- Would licensee compliance with the risk-informed regulation be amenable to regulatory oversight?
- Would the risk-informed regulation increase the number or complexity of inspections needed to ensure compliance?
- Would the risk-informed regulation necessitate changes in the agency's oversight program?
- Would assessment or monitoring be required?

Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would change the use of resources by its licensees include an accompanying regulatory analysis. In regard to relaxation of requirements, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (NUREG/BR-0058) states that a regulatory analysis should include a level of assessment that would demonstrate with sufficient reasonableness that the two following conditions are satisfied:

- The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented.
- The cost savings attributed to the action would be substantial enough to justify taking the action.

As part of the staff's activities, the role of regulatory analysis in the evaluation of risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework. In this regard, in response to Commission concerns about bundling individual requirements in proposed risk-informed changes to 10 CFR Part 50 (Option 3) and 10 CFR 50.44 (Combustible gas control for nuclear power reactors), the staff issued 69 FR 29187 (May 21, 2004).

4. Communication Plans

The agency recognizes that it must keep its staff, the public, and the nuclear industry informed about NRC regulatory activities. The staff has recognized the need to develop communication plans that will increase public confidence by prescribing methods of conveying information about the agency's programs and activities to the public. Specifically, integrated area-specific communication plans that cut across organizational boundaries and address the broad spectrum of agency efforts to risk-inform regulatory activities are needed, as well as activity-specific plans.

In response, the staff prepared and submitted to the OEDO in December 2000 a communication plan for risk-informing regulatory activities in the materials and waste safety areas. The stated purposes of the NMSS communication plan were (1) to communicate the major points of the program to risk-inform materials (and waste) regulations in order to increase public confidence in the NMSS efforts and (2) to communicate NMSS activities, tasks, and methodologies in a manner that increases understanding and acceptance of NMSS efforts within the NRC and assists colleagues in their task of presenting risk-related information. NMSS revised its communication plan in April 2002.

In March 2005, the staff completed the development of the risk communication guidelines which were coordinated with several other offices. Guidance and training to improve the communication of risk insights and information to all NRC stakeholders have been completed. "Guidelines for Internal Risk Communication" (NUREG/BR-0318) contains practical, how-to guidance for NRC staff and management on NRC-specific communication topics and situations that deal with risk. Risk communication training incorporates guidance from NUREG/BR-0318 and NUREG/BR-0308, "Effective Risk Communication," into a forum for learning and practicing risk communication skills.

5. Training Program

In the reactor safety area, the staff has already been given general training to increase its knowledge of and skills in probabilistic risk assessment. Training is available on an as-needed basis. In the nuclear materials and waste safety areas, the NRC's Office of Human Resources has identified, developed, and implemented staff training to ensure that the staff is fully prepared for risk-informed regulation.

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PART 2. RISK-INFORMED REGULATION IMPLEMENTATION ACTIVITIES

Part 2 of the RIRIP presents current risk-informed initiatives and activities organized by primary FY 04-09 strategic plan goal—in particular, safety, effectiveness, and openness. Part 2 of the RIRIP has three chapters: Chapter 1 addresses activities which support primarily the safety goal, Chapter 2 addresses activities which support primarily the effectiveness goal, and Chapter 3 addresses an activity which supports primarily the openness goal.

Each chapter provides individual, detailed discussions of the implementation activities, including project management considerations and more schedule and milestone information.¹

¹ The NRC responsible organizations listed in this report reflect the NRC organization as of September 2006. The RIRIP update submitted in April 2007 will reflect the revised NRC organization.

CHAPTER 1. SAFETY

Goal: Ensure Protection of Public Health and Safety and the Environment

Strategic Outcomes:

No nuclear reactor accidents.

No inadvertent criticality events.

No acute radiation exposures resulting in fatalities.

No releases of radioactive materials that result in significant radiation exposures.

No releases of radioactive materials that cause significant adverse environmental impacts.

1.1 Introduction

The NRC has generally regulated nuclear sites and facilities based on deterministic approaches. Deterministic approaches to regulation consider a set of challenges to safety and determine how those challenges should be mitigated. As discussed in Part 1 and in the Commission's PRA policy statement, a probabilistic approach to regulation enhances and extends this traditional, deterministic approach by (1) allowing consideration of a broader set of potential challenges to safety, (2) providing a logical means for prioritizing these challenges based on risk significance, and (3) allowing consideration of a broader set of resources to defend against these challenges.

According to the FY 04-09 Strategic Plan, "NRC's primary goal is to regulate the safe uses of radioactive materials for civilian purposes to ensure the protection of public health and safety and the environment. In response to anticipated developments in the nuclear arena over the next several years, the NRC will place significant emphasis on strengthening the interrelationship among safety, security, and emergency preparedness."

The NRC's regulatory actions apply to all licensees whether they use radioactive materials for power generation, reactor fuel production, medical therapies, industrial processes, research, or waste storage and disposal. The agency's regulatory activities are applied in a manner consistent with the risk presented by specific uses, incorporating sound science and operating experience to ensure that licensees have adequate safety margins. In carrying out its safety mission, the NRC takes all actions necessary to ensure that a licensee's performance does not fall below acceptable levels.

To meet the challenges to the agency's regulatory climate, NRC expects to adjust to both internal and external factors, such as the use of risk-informed and performance-based regulations. Some important considerations include materials degradation at nuclear power plants; licensing of new nuclear power plants; high-level waste transport, storage, and disposal; new and evolving technologies; and continual review of ongoing operational experience.

Other considerations will arise as the agency continually reviews domestic and international operational experience to help identify potential new licensee-specific or generic safety issues. It is the responsibility of the NRC to ensure that its licensees use radioactive materials safely. The NRC employs a multifaceted regulatory approach to safety that includes the following activities:

- Develop and update risk-informed and performance-based standards, as appropriate, and Federal regulations to enable the safe use of radioactive materials, using the "defense-in-depth" principles and appropriately conservative and realistic practices that provide an acceptable margin of safety.
- License individuals and organizations that intend to use radioactive materials for safe and beneficial civilian purposes.
- Maintain ongoing and consistent oversight of licensees, which includes inspection, enforcement, and incident response activities, to ensure that licensees are conforming to the applicable regulations and the conditions of their licenses to ensure safety and to provide timely and appropriate event assessment and response.

Until the accident at Three Mile Island (TMI) in 1979, the NRC (formerly the Atomic Energy Commission) only used probabilistic criteria in certain specialized areas of reactor licensing reviews. For example, human-made hazards (e.g., nearby hazardous materials and aircraft) and natural hazards (e.g., tornadoes, floods, and earthquakes) were typically addressed in terms of probabilistic arguments and initiating frequencies to assess site suitability. The "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (NUREG-0800) for licensing reactors and regulatory guides supporting NUREG-0800 provided review and evaluation guidance with respect to these probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. The accident led to a substantial research program on severe accidents. In addition, both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional nonprobabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (Probabilistic Risk Assessment Reference Document, NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

In early 1991, the NRC published NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In NUREG-1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants. This study was a significant turning point in the use of risk-based concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance after core damage and

accident progression. The methods developed for and the results of these studies provided a valuable foundation in quantitative risk techniques.

In the late 1990's, NRC's work to expand the use of PRA in regulatory processes has been documented in the PRA Implementation Plan (see SECY-99-211). Many early actions focused on the development of skills, tools, and infrastructure for applying risk information.

In considering what areas in the safety arena to target for greater use of risk information, the NRC staff examined the sources of risk, the existing regulatory processes, and where the best opportunities for improvements were. This led to a focus on reactors operating at power, but also gave consideration to (1) low-power and shutdown conditions, (2) reactors undergoing decommissioning with fuel stored in pools, and (3) advanced reactor designs. The staff has also started using PRA in the areas of materials and waste safety.

With the enhanced risk assessment capabilities, the staff also recognized that there were opportunities to reduce unnecessary regulatory burden. Stakeholder input was sought to identify burdensome areas in which risk information indicated that the burden may not be commensurate with the risks. Initial efforts focused on discrete areas to gain experience with use of the tools and guidance. As noted, the staff first developed the basic guiding principles (safety goal, PRA policy, and general guidance for licensing action decisions) and then proceeded with pilot applications. Over the last several years, the staff has reviewed individual licensing actions in such areas as graded quality assurance, inservice inspection, inservice testing, and changes to allowed outage times in the technical specifications. Having completed several pilots, the staff has concluded that more risk information could be used in the regulatory process in a manner that maintained safety, improved safety focus, and reduced unnecessary burden. Thus, the staff is now focusing on other activities such as rulemaking to offer voluntary options for licensees. These activities include both specific technical areas (e.g., fire protection, emergency core cooling system) and broader changes such as the adjustment of special treatment requirements.

Where necessary, the staff has also added requirements as a result of risk information; for example, the maintenance rule (10 CFR 50.65) was modified to require licensees to assess and manage the increase in risk that may result from maintenance activities.

Risk information is being used to focus staff inspection and enforcement activities and to adjust specific requirements on licensees. For example, the risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures, and components and to develop processes for determining the risk significance of inspection findings. For instance, in determining the areas to be inspected and the amount of inspection effort to apply, the staff considered the risk significance of the activities or systems involved. Further, risk information was used where possible in setting the thresholds for the performance indicators. When judging the importance of inspection findings, the Significance Determination Process uses risk information to assess the significance of the issue. These assessments are then input to an assessment process to define the agency response – depending on the significance of individual findings and overall plant performance.

The staff has also been using risk information for several years for event assessment. For example, the Accident Sequence Precursor Program determines conditional core damage probability for particular events or plant conditions. Finally, the staff is continuing various research programs to enhance its capabilities to conduct or review risk analyses. These

research programs include activities to improve tools, enhance data, and identify areas where requirements can be adjusted in a risk-informed manner.

Prioritization of RIRIP Implementation Activities

In response to the Commission's direction in the January 4, 2001, SRM on the October 2000 version of the RIRIP, the priority rating is listed under each implementation activity. Staff activities are rated in relation to supporting the strategic plan goals. These priorities were determined through the planning, budgeting, and performance management (PBPM) process. As part of the FY 2006 PBPM process, the program offices developed a common prioritization methodology and used it to produce a prioritized list of planned activities. The offices continued to use the common prioritization methodology to plan, budget, and implement RIRIP activities. As with other staff activities, priorities of the staff's risk-informed regulation implementation activities will continue to be adjusted in a way consistent with the PBPM process to reflect changes to the agency budget and priorities.

The prioritization in this RIRIP update is based on the FY 2008 PBPM process. NRC FY 2004- FY 2009 Strategic Plan goal priorities are listed as "high," "medium," or "low."

1.2 Safety Strategies

The NRC will employ the following strategies to ensure protection of public health and safety and the environment:

- (1) Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste-related activities to protect public health, safety, and the environment.
- (2) Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.
- (3) Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.
- (4) Utilize regulatory programs and applied research effectively to anticipate and resolve safety issues.
- (5) Evaluate and utilize domestic and international operational experience and events to enhance decisionmaking.
- (6) Conduct NRC safety oversight programs, including inspections and enforcement activities, to monitor licensee performance.

1.3 Current Safety Initiatives and Activities

Risk-informing initiatives/activities whose primary NRC FY 2004- FY2009 Strategic Plan goal is safety:

SA-1 Maintain a risk-informed assessment process for determining NRC actions based upon performance indicators and inspection information

SA-2 Reactor Oversight Process support (renamed EF-20)

- SA-3 Industry Trends Program support
- SA-4 Reactor Performance Data Collection Program
- SA-5 Accident Sequence Precursor Analysis Program
- SA-6 SPAR Model Development Program (renamed EF-21)
- SA-7 Incorporate risk information into the high-level waste regulatory framework.
- SA-8 Change technical requirements of 10 CFR 50.46 (renamed EF-22)
- SA-9 Digital systems probabilistic risk assessment
- SA-10 Develop risk-informed improvements to standard technical specifications (STS)
- SA-11 Fire protection for nuclear power plants
- SA-12 Incorporate risk information into the decommissioning regulatory framework
- SA-13 Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking
- SA-14 Evaluation of loss-of-offsite-power (LOOP) events and station blackout.(completed)
- SA-15 Exemptions from licensing and distribution of byproduct material: licensing and reporting requirements
- SA-16 Materials licensing guidance consolidation and revision
- SA-17 Implementation of Part 70 revision
- SA-18 Assessing performance of steam generator tubes and other reactor coolant system (RCS) components during severe accidents.

These initiatives/activities are described in detail on the following pages. The descriptions include project considerations, such as priority, schedule and milestones, and special considerations (e.g., training, stakeholder communications, external dependencies).

SA-1 Safety Strategic Plan Goal

Implementation Activity: Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information. (NRR/ADRO/DIRS)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 6: Conduct NRC safety oversight programs, including inspections and enforcement activities, to monitor licensee performance.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Primary Priority: Medium

Secondary Priority: High

The Reactor Oversight Process (ROP) was developed using the results of research work and previous risk studies to identify the most significant structures, systems, and components (risk matrices) and to develop processes by which inspection findings could be risk-informed (Significance Determination Process). Risk significance is considered in determining the amount of inspection effort to be applied.

The basic approach under the Reactor Oversight Process (ROP) is to monitor licensee performance with respect to reactor safety cornerstones (initiating events, mitigation systems, barrier integrity, and emergency preparedness), radiation safety cornerstones (occupational radiation exposure and public radiation exposure), and the security cornerstone. In addition to the inspection program, performance indicators (PIs) are also in place to monitor licensee activities in the established cornerstones not reviewed by the inspection process. Licensee performance is assessed by combining the outcome, based on significance thresholds, of the performance indicators and inspection findings. Depending on the assessment results, inspection resources may be expended to focus on licensees with degraded or declining performance.

The results and lessons learned from ROP implementation are documented in annual reports to the Commission. The latest report is Assessment Cycle 6, January 2005 through December 2005 (SECY-06-0074).

Risk information is used where possible in setting the thresholds for the performance indicators. The Significance Determination Process (SDP) uses risk information to assess the safety significance of inspection findings. SDP tools were developed to characterize the safety significance of issues associated with reactor safety at-power operations, emergency preparedness, occupational and public radiation safety, physical protection, fire protection, shutdown risk, containment integrity, operator requalification, maintenance, and steam generator tube integrity. These SDP tools either use quantitative risk evaluations or are risk informed.

The reactor safety SDP risk-informed Phase 2 notebooks incorporate the methodology to risk-inform findings associated with the reactor safety at-power operations. Revision 2 of the 71 notebooks were placed on the NRC internal Web site along with the newly developed pre-solved tables in December 2005. Official implementation of the revised notebooks and pre-solved tables will take place October 2006 following a short training period. Revision 2 of the notebooks represents a significant staff effort for standardization of the methodology and addresses changes in the licensees' probabilistic risk analyses (PRAs) to date. It is expected that the notebooks will continue to be evaluated in response to future licensee-implemented changes to the plant.

The pre-solved tables (i.e., spreadsheets) contain a comprehensive target set of approximately 40 to 50 plant-specific key components and operator actions. Selection of the target set items was based, in part, on components and equipment issues typically encountered in ROP inspection activities or the items were selected to test the notebook's model and logic. The spreadsheet essentially represents the solution and answer key to these target set items. The staff incorporated large early release frequency (LERF) risk aspects in both the notebooks and the associated spreadsheets.

A methodology has been developed to account for the added risk contribution from external events, and is under final consideration. Based on a pilot program, two potentially viable methodologies are being pursued. An assessment tool incorporating one of the methodologies for use by inspectors and senior resident analysts (SRAs) is several years away. A simple methodology to help inspectors evaluate the risk contribution from external initiators as part of the reactor safety Phase 2 process is also being contemplated but is not currently available.

Project Considerations: A Mitigating Systems Performance Index (MSPI) was jointly developed by NRC staff and industry and was evaluated for implementation. The component outliers identified from standardized plant analysis risk (SPAR) and licensee PRA model comparisons were resolved to allow the staff to implement MSPI at all operating reactors on April 1, 2006.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Next annual status report on ROP implementation	April 2007			NRR/ADRO/DIRS/IRIB (P. Koltay, x0213)
Revise inspection procedures to incorporate lessons learned from Davis-Besse Lessons Learned Task Group	March 2004	January 2005	January 2005	NRR/ADRO/DLR/RLR (R. Mathew, x2965)
Test effectiveness of newly developed inspection procedure for engineering design inspections (SECY-04-0071)	March 2005	September 2005	June 2005	NRR/ADRO/DIRS/IPAB (D. Norkin, x2954)
Maintain and improve SDP inspection notebooks (Revision 2)	June 2005	October 2005	December 2005	NRR/ADRA/DRA/APOB (R. Perch, x1422)
Develop the SDP Phase 2 pre-solved tables	December 2005	September 2006	October 2006	NRR/ADRA/DRA/APOB (R. Perch, x1422)
Implement the MSPI	January 2006	April 2006	April 2006	NRR/ADRO/DIRS/IPAB (J. Thompson, x1011)
Develop external event assessment tool for SDP	TBD			NRR/ADRA/DRA/APOB (J. Kramer, x1173)

SA-3 Safety Strategic Plan Goal

Implementation Activity: Industry Trends Program Support (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decision-making.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Strategy 7: Anticipate challenges and respond quickly to changes in the regulatory and technical environment.

Primary Priority: High

Secondary Priority: Medium

The NRC's Industry Trends Program (ITP) monitors trends in indicators of industry performance to confirm that the safety of operating power reactors is being maintained. If any long-term indicators show a statistically significant adverse trend, the NRC will evaluate the trends and take appropriate regulatory action using its existing processes for resolving generic issues and issuing generic communications.

RES supports the ITP by analyzing and trending the operating experience data in RES databases. This includes updating trends for initiating events, component and systems reliabilities, common-cause failures, and fire events, and then providing this information on the RES internal and public Web sites.

RES has continued development of the Baseline Risk Index for Initiating Events (BRIIE) which is an industry- wide risk-informed performance indicator for initiating events. Development will address differences between the BRIIE calculations and the comparable Mitigating Systems Performance Index (MSPI) methodology that is being developed to support the Reactor Oversight Process (ROP). An internal panel has reviewed the BRIIE and set tentative thresholds for BRIIE. The panel also provided recommendations regarding the form of BRIIE and its display. The staff's goal is to present BRIIE results and thresholds in the FY 2006 ITP paper (to be issued in early CY 2007) and incorporate BRIIE into the ITP and formally use BRIIE results as an ITP indicator in the FY 2007 ITP paper (to be issued in early CY 2008.)

RES published a "Reevaluation of Station Blackout Risk at Nuclear Power Plants ", (NUREG/CR-6890) that updated previous reports analyzing loss of offsite power (LOOP) events and the associated station blackout (SBO) core damage risk at U.S. commercial nuclear power plants. LOOP data for 1986 - 2004 were collected and analyzed.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Update the NRC Web page and provide to NRR updated trends, graphs, and charts for system studies, component studies, common-cause failure evaluations, and initiating event evaluations through FY 2004.	November 2005		November 2005	RES/DRAA/OERAB
Provide to NRR the updated program plan for implementing the Baseline Risk Indicator of Initiating Events (BRIIE).	March 2006		March 2006	RES/DRASP
Provide to NRR for review and comments the draft NUREG report for the Baseline Risk Indicator for Initiating Events	November 2006			RES/DRASP
Update the NRC Web page and provide to NRR updated trends, graphs, and charts for system studies, component studies, common-cause failure evaluations, and initiating event evaluations through FY 2005.	November 2006			RES/DRASP
Submit to Publications the final NUREG/CR for the baseline risk indicator for initiating events	January 2007			RES/DRASP

SA-4 Safety Strategic Plan Goal

Implementation Activity: Reactor Performance Data Collection Program (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decision-making.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Primary Priority: High

Secondary Priority: Medium

Data are collected on the operation of nuclear power plants from licensee event reports (LERs), licensee monthly operating reports (MORs), NRC inspection reports, and industry databases. The data collected include component and system failures, demands on safety systems, initiating events, fire events, and common-cause failures. The data and data analysis results are stored in database systems for use by the NRC staff as part of other regulatory processes to help identify potential safety issues. These processes include the Industry Trends Program (ITP), the Accident Sequence Precursor (ASP) Program for evaluating the risk associated with operational events and/or degraded conditions, and the Reactor Oversight Process (ROP). In addition, the data are used as input for the risk assessment models known as Standardized Plant Analysis Risk (SPAR) models. The database systems include the Integrated Data Collection and Coding System (IDCCS), the Reliability and Availability Data System (RADS), the Common-Cause Failure Database, the Fire Events Database, and the Accident Sequence Precursor (ASP) Events Database.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Integrated Data Collection and Coding System has been maintained with the latest FY2005 data available through August 2005.	September 2005		September 2005	RES/DRAA/OERAB
Memorandum to the Operating Experience Clearinghouse stating that the Integrated Data Collection and Coding System has been maintained with FY 2005 data.	December 2005		December 2005	RES/DRAA/OERAB
Memorandum to the Operating Experience Clearinghouse to inform and update agency users of INPO's EPIX database system.	February 2006		February 2006	RES/DRASP
Memorandum to NRR and the regions documenting common-cause data evaluation.	August 2006		August 2006	RES/DRASP
Integrated Data Collection and Coding System testing completed and modification to a more integrated and efficient coding and structure	September 2006		September 2006	RES/DRASP
Integrated Data Collection and Coding System has been maintained with the latest FY2006 data available through August 2006.	September 2006		September 2006	RES/DRASP
Final draft of update of NUREG/CR-6268/CR, "Common Cause Failure Database and Analysis System	October 2006			RES/DRASP
Memorandum to the Operating Experience Clearinghouse stating that the Integrated Data Collection and Coding System has been maintained with FY 2006 data	December 2006			RES/DRASP

SA-5 Safety Strategic Plan Goal

Implementation Activity: Accident Sequence Precursor (ASP) Program (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decision-making.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 4: Use realistically conservative, safety-focused research programs to resolve safety-related issues.

Primary Priority: High

Secondary Priority: Medium

The risk associated with operational events and/or degraded conditions is evaluated under the Accident Sequence Precursor (ASP) Program by systematically reviewing and evaluating operating experience to identify precursors to potential severe core damage sequences, documenting precursors, categorizing them by plant-specific and generic implications, and providing a measure of trends in nuclear plant core damage risk. The objectives of the ASP Program are to determine the safety significance of events and their regulatory implications; provide feedback to improve probabilistic risk assessment (PRA) models; and provide NRC Strategic Plan performance measures and the ASP occurrence rate trending for the annual Performance and Accountability Report to Congress. Since its inception, the ASP Program has evaluated more than 650 precursors, which are maintained in the ASP Events database.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Provide to the EDO the annual SECY paper on the status of the ASP Program and the SPAR model development program.	September 2006		September 2006	RES/DRASP/OEGIB
Provide OCFO input on significant precursors through June 2006.	October 2006			RES/DRASP/OEGIB
Provide ASP trends through FY 2005 to NRR to support the Industry Trends Program.	November 2006			RES/DRASP/OEGIB
Provide latest results on ASP trends and number of significant precursors to support Agency Action Review Meeting (AARM).	April 2007			RES/DRASP/OEGIB
Provide to the EDO the annual SECY paper on the status of the ASP Program and the SPAR model development program.	September 2007			RES/DRASP/OEGIB

SA-7 Safety Strategic Plan Goal

Implementation Activity: **Incorporate Risk Information Into the High-Level Waste Regulatory Framework (NMSS/HLWRS/TRD)**

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Primary Priority: High

Secondary Priority: High

Description of Activity:

The Yucca Mountain Review Plan (NUREG-1804, Rev 2, 2003) provides guidance to staff on implementing the risk-informed, performance-based regulations of 10 CFR Part 63. The staff will use the Yucca Mountain Review Plan to ensure that licensing reviews are risk-informed and the proper level of effort is focused on areas important to the safety of the potential geologic repository at Yucca Mountain, Nevada.

The staff completed the risk insights initiative in April 2004 and sent the Commission the Risk Insights Baseline Report. The Risk Insights Baseline Report provides an overall integrated perspective for evaluating the risk significance of repository issues and systems down to the subsystem level. The risk insights report is used to focus pre-licensing activities on significant key technical issues. There were 293 agreements with the U.S. Department of Energy related to the key technical issues. These agreements were developed to assure incorporation of sound science into a review of the Yucca Mountain license application. Using this report, the NRC staff finished the evaluation of high-ranked agreements in December 2004. The staff also finished the review of most moderate to low ranked agreements in April 2005. Currently 256 are complete, 29 need additional information and require responses from the U.S. Department of Energy, and 8 are on hold pending the U.S. Department of Energy's resolution of the U.S. Geological Survey quality assurance issues involving the infiltration model. Additional response from the U.S. Department of Energy has been received for two of the 29 agreements which required additional information, and responses to these agreements are being prepared. Evaluations for the remaining agreements will be completed after the U.S. Department of Energy provides responses for additional information needs and resolves the U.S. Geological Survey quality assurance issues. Staff will continue to use risk insights to evaluate any issues that may arise

from potential changes to the U.S. Department of Energy's demonstration for pre-closure and post-closure performance and from considerations for time periods beyond 10,000 years.

In addition, the staff developed a License Application Project Plan in December 2004 to guide the process for conducting and documenting the license application review. Staff will use the License Application Project Plan along with the Yucca Mountain Review Plan, the Risk Insights Baseline Report, and the Integrated Issue Resolution Status Report to guide development of specific review strategies for each of the model abstraction review teams. The staff also used risk insights to develop a risk-informed Yucca Mountain inspection program in September 2005. Staff continues refining the current total-system performance assessment (TPA) code to facilitate calculations beyond 10,000 years, to incorporate proposed revisions to the regulatory requirements specified in 10 CFR Part 63, and to accommodate a review of potential U.S. Department of Energy design changes. The staff intends to refine the risk insights baseline as risk information becomes available and to utilize the baseline in reviewing a Yucca Mountain license application and conducting other regulatory activities.

Project Considerations: NRC's High-Level Waste program activities and milestones anticipated for Fiscal Year 2007 will be affected by external factors such as the delay of a license application for an High-Level Waste repository by the U.S. Department of Energy from December 2004 and uncertainties in the development of revised the U.S. Environmental Protection Agency's radiation protection standards for Yucca Mountain (40 CFR Part 197) as a result of public comment.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Develop HLW inspection procedures using risk insights (complete seven integrated inspection procedures)	September 2004	December 2005	September 2005	NMSS/HLWRS/TRD
Complete risk-informed pre-closure and post-closure key technical issue resolution activities using risk insights	April 2005 [†]	TBD ^{††}		NMSS/HLWRS/TRD
Develop model abstraction review team strategies using risk insights	September 2006	December 2006		NMSS/HLWRS/TRD
Develop Total-system Performance Assessment (TPA) code, Version 5.1	September 2006	June 2007		NMSS/HLWRS/TRD

[†] Staff addressed all 293 Key Technical Issue Agreements using risk insights in April 2005 (see description for more detail).

^{††} Revised date will be established pending resolution of the U.S. Geological Survey quality assurance issues and receipt of the U.S. Department of Energy responses to agreements previously identified as needing additional information. This date will also consider the need for risk-informed resolution of potential issues arising from proposed revision of 10 CFR Part 63 and from DOE modifications to repository design, operations, approaches, methods, and models during pre-licensing. The U.S. Department of Energy has informed NRC that information on agreements which have additional information needs will be provided in the near future.

SA-9 Safety Strategic Plan Goal

Implementation Activity: **Digital Systems Probabilistic Risk Assessment: Develop methods and tools for analyzing digital systems reliability that are consistent with a risk-informed approach to decisionmaking. (RES/DFERR, RES/DRASP)**

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 4: Utilize regulatory programs and applied research effectively to anticipate and resolve safety issues.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 4: Use realistically conservative, safety-focused research programs to resolve safety-related issues.

Primary Priority: Medium

Secondary Priority: Medium

Licenses are currently replacing their original analog control, instrumentation, and protection systems with digital systems. There are no widely accepted methods for including software failures of real-time digital systems into current generation probabilistic risk assessments (PRAs). The RES staff, with the support of the Ohio State University, the University of Virginia and the Brookhaven National Laboratory, will develop both traditional and dynamic methods of modeling the reliability of digital systems that can be integrated into current PRAs. This research has three parts. The first part of the research is based on traditional approaches (e.g., fault tree and Markov methods) and includes:

- (a) Review of approaches used in the nuclear industry and other industries for reliability modeling of digital systems
- (b) Development of a suitable reliability model for digital system hardware
- (c) Development of a suitable reliability model for digital system software
- (d) Integration of the hardware and software models for digital systems
- (e) Integration of the combined model into a PRA

- (f) Complete a benchmark study using the methods developed to assess the capabilities and limitations of the methods

The second part of the research will use dynamic reliability methods such as Dynamic Flowgraph Methodology to model digital systems and includes:

- (a) Assessment of the current state of dynamic reliability methods
- (b) Development of dynamic modeling requirements
- (c) Determination of a method to identify system state and transition rates
- (d) Quantification of system failure probabilities
- (e) Integration of the methods into a PRA
- (f) Complete a benchmark study using the methods developed to assess the capabilities and limitations of the methods

The research on both the traditional and dynamic methods will include performing case studies using the Calvert Cliffs Nuclear Power Plant digital feed-water control system and a Nuclear Power Plant's reactor protection system, which is based on one of the generically approved digital platforms. This work will help ensure that the methods and tools that are being developed for analyzing digital systems reliability are consistent with a risk-informed approach to decisionmaking. It is expected that there will be some digital systems that can be modeled by the traditional methods; however, there may be some digital systems that can only be modeled using dynamic methods.

The third part of the research will be to develop additional regulatory guidance to support the use of risk-informed review of digital systems.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Letter report on the review of the following reports to identify insights and issues on modeling digital systems: EPRI-1002835, EPRI TR-107330, International Electrotechnical Commission Standard (IEC) 61508, and IEC 61511.	June 2005		June 2005	RES/DRASP
Letter report on how each agency/industry models reliability of digital systems, including failure data, and how the models are used in making decisions.	August 2005		August 2005	RES/DRASP
Letter report on the development of a preliminary database for quantifying PRA models of digital systems. The report will include a collection of digital failure databases and will describe their use in probabilistic modeling of digital systems, how existing databases could be used to model digital systems, and additional data collection and analysis needed to improve the currently available data.	August 2005		August 2005	RES/DRASP
NUREG/CR that documents the assessment of the current state of dynamic reliability methods as they apply to digital system modeling and the development dynamic modeling requirements for digital systems.	October 2005		October 2005 published February 2006	RES/DFERR
NUREG/CR that documents the development of a method to identify system state and transition rates and quantify system failure probabilities for dynamic methods.	April 2006		April 2006 to be publish January 2007	RES/DFERR
Draft regulatory guide on risk-informed digital system reviews published for public comment.	June 2006	TBD		RES/DFERR
Draft report that documents the preliminary analysis on the review of software-induced failure experience	August 2006		June 2006	RES/DRASP
Letter report that will review software- induced failure experience.	November 2006			RES/DRASP
Complete Benchmark of dynamic reliability modeling methods	November 2006	TBD		RES/DFERR
Draft report that documents the basis for using software failure rates and probabilities in probabilistic failure modeling of digital systems.	November 2006			RES/DRASP

SA-10 Safety Strategic Plan Goal

Implementation Activity: Develop risk-informed improvements to the standard technical specifications (STS). (NRR/ADRO/DIRS)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste-related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Primary Priority: Medium

Secondary Priority: High

Consistent with the Commission's policy statements on technical specifications and the use of PRA, the NRC and industry continue to develop risk-informed improvements to the current standard technical specifications (STS). These improvements are intended to maintain or improve safety while reducing unnecessary burden and to make technical specification requirements consistent with the Commission's other risk-informed regulatory activities.

Proposals for risk-informed improvements to the STS are judged based on their ability to maintain or improve safety, the amount of unnecessary burden reduction they will likely produce, their ability to make NRC's regulation of plant operations more efficient and effective, the amount of industry interest in the proposal, and the complexity of the proposed change.

To date the industry and the staff have identified eight initiatives for risk-informed improvements to the STS: (1) define the preferred end state for technical specification actions (usually hot shutdown for PWRs); (2) increase the time allowed to delay entering required actions when a surveillance is missed; (3) modify the existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk); (4) modify the current system of fixed completion times to allow reliance on a configuration risk management program (CRMP) to determine risk-informed completion times; (5) optimize surveillance frequencies; (6) modify LCO 3.0.3 actions to allow a risk-informed evaluation to extend operating time prior to shut down; (7) define actions to be taken when equipment is not operable but is still functional; and (8) risk-inform the scope of the TS rule.

Each initiative can involve some combination of a topical report approving the generic change; an STS change proposal with a TSTF-### designator; a pilot plant to test the change; and a Consolidated Line Item Improvement Process (CLIIP) package (described in NRC Regulatory Issue Summary 2000-06, "Consolidated Line Item Improvement Process for Adopting Standard Technical Specifications Changes for Power Reactors," for reviewing and implementing improvements to the STS). The four owners groups may or may not consolidate efforts into a single submittal. The following table on "Selected Major Milestones and Schedules" reflects upcoming targeted completion dates.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Initiative 1: Approve TSTF-422 for CE plants and make available via CLIIP	September 2003	July 2005	July 2005	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Complete review of TSTF-423 for BWR plants	March 2005	March 2006	March 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Write safety evaluation for B&W topical report	December 2004	July 2006	August 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Complete review of TSTF-431 for B&W plants and make available via CLIIP	June 2005	March 2007		NRR/ADRO/DIRS
Initiative 4: Industry submit revised Risk Management Guide, CE (TSTF-424), and STP pilot amendment	June 2004	October 2006		N/A
Initiative 5: Industry submit methodology document, Limerick pilot amendment and TSTF-425	March 2004	July 2005	February 2005	N/A
Initiative 5: Complete review of methodology document, Limerick pilot amendment, and TSTF-425	October 2005	September 2006	September 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)

Initiative 6: Complete review of TSTF-426 and make available via CLIP	December 2004	January 2007		NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Make TSTF -372 (snubbers) available via CLIP	December 2004	May 2005	May 2005	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Complete review of TSTF -427 (hazard barriers) and write safety evaluation	October 2005	March 2006	March 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Make TSTF -427 (hazard barriers) available via CLIP	December 2005	September 2006	September 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 8: Relocate Non-Risk Systems from TS	TBD			NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)

SA-11 Safety Strategic Plan Goal

Implementation Activity: Fire protection for nuclear power plants (NRR/ADRA/DRA)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 4: Use realistically conservative, safety-focused research programs to resolve safety-related issues.

Primary Priority: High

Secondary Priority: High

Subactivity 1: National Fire Protection Association Standard NFPA 805 Rule and Regulatory Guide

The staff completed the rulemaking to endorse an alternative performance-based and risk-informed fire protection rule for operating nuclear power plants. The staff worked with the National Fire Protection Association (NFPA) to develop NFPA Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," 2001 Edition. The final rule to incorporate NFPA 805 standard 2001 Edition into 10 CFR Part 50 § 50.48(c) was published in the *Federal Register* in June 2004 and became effective on July 16, 2004. Nuclear Energy Institute (NEI) developed an implementation guide, NEI 04-02, Revision 1, "Guidance for Implementation a Risk-Informed, Performance-Based Fire Protection Program Under 10 CFR 50.48(c)." In May 2006, NRC endorsed issued Regulatory Guide 1.205, "Risk-Informed, Performance-Based Fire protection For Existing Light-Water Nuclear Power Plants," This Regulatory Guide endorsed NEI-04-02. To date, 40 operating nuclear power plants have decided to adopt this alternative rule.

Subactivity 2: Post-Fire Safe-Shutdown Circuit Analysis Resolution Program

Another activity related to fire protection is the Circuit Analysis Resolution Program. In response to the need to resolve concerns associated with post-fire safe-shutdown fire-induced circuit failure analysis issues, the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) have respectively developed deterministic and risk-informed post-fire safe-shutdown methodology documents. These two documents have been combined into one document NEI 00-01,

“Guidance for Post-Fire Safe Shutdown Analysis,” which provides a method for determining the potential risk for circuit failure during a postulated fire.

NEI and Electric Power Institute (EPRI) completed a series of fire tests which provided insights into electrical cable performance and subsequent failures during a thermal insult. NEI/EPRI also convened an expert panel to evaluate the test results. NEI/EPRI published this work in May 2002 as “Spurious Actuation of Electrical Circuits Due to Cable Fires” (EPRI Technical Report 1006961). NEI submitted NEI 00-01, Revision 1, to the staff in December 2004. The staff has reviewed this document and endorsed a portion of the document

With respect to post-fire safe-shutdown electrical circuit inspections, NRR held a facilitated workshop in February 2003 to discuss and exchange information with stakeholders concerning risk-informing the inspections. The staff subsequently held a workshop for regional inspectors in July 2004, and conducted another public workshop in October 2004, to explain the risk-informed inspections. The staff issued Revision 1, to RIS 2004-03, “Risk-Informed Approach for Post-Fire Safe-Shutdown Circuit Inspections,” on December 29, 2004, which includes the risk-informed inspection process and notification to licensees that circuit inspections would resume in January 2005. Subsequently, the staff issued a second RIS 2005-30, “Clarification of Post-Fire Safe-Shutdown Circuit Regulatory Requirements,” December 2005, to clarify compliance expectations with regard to circuit analysis.

In addition, to bring closure to circuit failure issues and to support the resumption of circuit analysis inspections, the staff issued draft Generic Letter (GL) 2005-XX, “Post-Fire Safe-Shutdown Circuit Analysis Spurious Actuations,” in October 2005. This GL clarify regulatory requirements related to post-fire safe-shutdown circuit analyses, particularly the requirements of 10 CFR 50, Appendix R. Positions presented in this GL are based on the current regulations and are supported by the industry cable fire test results. The final GL on circuits will issue in October 2006.

Project Considerations: Improvements to fire PRA methods are critical to these efforts.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Subactivity 1: Issue final regulatory guide for the risk-informed, performance-based fire protection rule, 10 CFR § 50.48(c)	July 2005	May 2006 **	May 2006	NRR/ADRA/DRA/AFP (N. Iqbal, x3346)
Issue final generic letter on safe-shutdown circuit analysis, if approved by the Commission	October 2006			NRR/ADRA/DRA/AFP (E. McCann, x1218)

** Delayed due to receipt of NEI input and resolution of ACRS comments.

SA-12 Safety Strategic Plan Goal

Implementation Activity: Incorporate Risk Information Into the Decommissioning Regulatory Framework. (NMSS/DWMEP/DURLD)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 2: Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

During FY 2003 the staff completed the license termination rule (LTR) analysis (SECY-03-0069) and the Decommissioning Program evaluation. The LTR analysis was an assessment of LTR implementation issues and resulted in recommendations to resolve the issues, which the Commission approved in November 2003. In the Decommissioning Program evaluation the staff assessed the program effectiveness and recommended ways to further improve the management of the program. Both of these assessments included specific ways to further risk-inform the Decommissioning Program. For the LTR analysis the recommendations included (1) applying a risk-informed graded approach for using institutional controls to restrict the future use of a site and designing engineered barriers; (2) selecting more realistic exposure scenarios using a risk-informed approach; and (3) ranking operating sites and activities to focus NRC inspections and licensee monitoring and reporting on eliminating the possibility of difficult and costly decommissioning problems at future legacy sites. The Decommissioning Program evaluation recommended (1) implementing the Consolidated Decommissioning Guidance (completed in FY 2003) and emphasizing the risk-informed approach with staff and licensees, including developing examples, case histories, and lessons learned to illustrate the risk-informed approach; and (2) defining and managing all decommissioning sites using a graded approach to prioritize, allocate, and track both licensing and inspection resources based on site-specific risk insights and decommissioning challenges.

These assessments were a first step in a number of planned activities to be conducted during FY 2004-FY 2006 to implement all the LTR analysis and program evaluation recommendations, including those identified to further risk-inform the program. During FY 2004, the staff completed two implementation plans to identify the specific activities and schedules for each of the recommendations and thus define the specific work over the next few years. These recommendations were combined into the Integrated Decommissioning Improvement Plan (IDIP) during FY 2005. In general, for the LTR analysis recommendations, in FY 2004, the staff completed a regulatory issue summary of the LTR issues, Commission-approved recommendations, and the general implementation schedule for

our licensees and other stakeholders. As described in SECY-03-0069, the staff will develop guidance for staff licensing reviews that will give further details about the risk-informed approaches to institutional controls, engineered barriers, and exposure scenarios. The draft guidance for these topics was completed in FY 2005 and will be finalized in FY 2006. In addition, risk-informed general guidance for inspections and enforcement activities was developed in FY 2005. During the guidance development, however, the staff will continue to implement these new approaches at specific sites. The site-specific lessons learned are expected to enhance the guidance development process.

For the two program evaluation recommendations, the staff has developed training on aspects of the Consolidated Decommissioning Guidance and the risk-informed approach, and will continue to improve and expand training. Staff training, a general licensee workshop, and specific licensee meetings were performed during FY 2005. Staff training and site-specific meetings with licensees have continued in FY 2006. Site-specific meetings will be customized to address the needs of the licensees and the stage of decommissioning. During FY 2005, the staff developed a prioritization approach including risk insights to improve the management of decommissioning resources.

Primary Priority: Medium

Secondary Priority: Medium

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Risk-informed general inspection guidance	September 2005		September 2005	NMSS/DWMEP/DURLD
Final review guidance for institutional controls, engineered barriers, and realistic scenarios	September 2006		September 2006	NMSS/DWMEP/DURLD

SA-13 Safety Strategic Plan Goal

Implementation Activity: Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decisionmaking

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Consistent with the Commission's policy statements on the use of PRA and for achieving an appropriate quality for PRA's for NRC risk-informed regulatory decisionmaking, the NRC has ongoing activities to improve the quality of human reliability analysis (HRA). The adequacy of data available for HRA is a concern of practitioners and decision makers. To address this need, RES is developing, with the support of the Idaho National Laboratory (INL) the Human Event Repository and Analysis (HERA) system supporting both human factors and HRA applications. This activity is included as an item in the "Action Plan—Stabilizing the PRA Quality Expectation and Requirements," Appendix to SECY-04-0118, and it is being pursued through strong interactions with NRC, national and international experts.

The objective of HERA is to make available empirical and experimental human performance data, from commercial nuclear power plants (NPPs) and other related technologies, in a content and format suitable to human reliability analysis (HRA) and human factors practitioners.

The development of HERA has three aspects: (a) determine a structure for collecting information on human performance during abnormal conditions suitable for HRA and human factors, (b) populate HERA with information from nuclear power plants and other settings, and (c) identify and/or develop mathematical structures enabling the use of HERA data in HRA applications. The staff published NUREG/CR-6903, Vol. 1, "Human Event Repository and Analysis (HERA) System, Overview, July 2006. This Volume discusses the need for a systematic collection of human performance data on the

basis of current regulatory HRA and human factors applications, describes the taxonomy and structure of the data in HERA, and presents examples of information extraction and coding from nuclear power plant operational and simulator experience. Future Volumes will document the gathering of information from other technologies, such as chemical, military, aerospace, aviation, and the behavioral sciences, the quality assurance process of event coding, and the software implementation of HERA. The staff continues populating HERA with human events.

The development of mathematical structures enabling the use of HERA data in HRA is also being pursued through the use of Bayesian framework. A motivation for using the Bayesian framework comes from the fact that HRA deals with the identification, modeling, and quantification of human failure events related to crew response to an accident, which are rare events in the nuclear power industry and, therefore, directly relevant data on their likelihood are limited or even non-existent. The Bayesian methodology has proved to be particularly useful for disciplines dealing with the modeling of rare events because of its ability to make use of *evidence* (instead of actual occurrences) from various sources, including evidence that may be characterized as sparse or even incomplete. Hence, it appears to be the framework with which we can make use of the data gathered in HERA to improve our modeling of human performance and to better estimate the HEPs of interest in nuclear applications settings.

The staff held an expert workshop in Washington, D.C., August 2005, to discuss approaches to the use of data and forms of evidence to support the prediction of human performance in PRA applications. These discussions emphasized the use of Bayesian methods and experts presented different Bayesian-type approaches which were documented in a draft report submitted for external review in August 2006. This draft report will be revised per external review comments and will be submitted to publication in May 2007.

Primary Priority: Medium

Secondary Priority: High

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Revise HERA structure and NUREG/CR on HERA system and submit for formal NRC review	March 2004		March 2004	
Letter report on HRA data repository entitled Human Event Repository and Analysis (HERA) Framework with a proposed structure	September 2004	December 2004	December 2004	RES/DRASP
Populate HERA with human events from licensee event reports and release to NRC users--continual effort	December 2004	September 2005	September 2006	RES/DRASP
Support the international activities (CNSI and Halden) for HRA data development--continual effort	December 2004	September 2005	September 2006	RES/DRASP
Internal-NRC workshop on HERA structure	May 2005		May 2005	
Draft NUREG/CR on HERA system	September 2005		September 2005	RES/DRASP
Draft report on proposed Bayesian approaches for estimating human failure event probabilities using HERA	December 2005		November 2005	RES/DRASP
Submit to publication NUREG/CR-6903, Vol. 1, "Human Event Repository and Analysis (HERA) System, Overview."	May 2006		July 2006	RES/DRASP
Release for external review draft NUREG/CR report on Bayesian approaches for HRA	August 2006		August 2006	
Submit to publication a NUREG/CR report on Bayesian approaches for HRA	May 2007			

SA-15 Safety Strategic Plan Goal

Implementation Activity: Exemptions from licensing, general licenses, and distribution of byproduct material: licensing and reporting requirements (NMSS/IMNS/RGB)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 2: Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Primary Priority: Medium

Secondary Priority: Medium

The staff conducted a systematic re-evaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, which govern the use of byproduct and source materials. A major part of the effort was an assessment of potential and likely doses to workers and the public under these exemptions. The assessment of doses associated with most of these exemptions was published as NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," June 2001. NUREG-1717 also includes dose assessments for certain devices currently used under a general or specific license that had been identified as candidates for use under exemption. The results of this study have been considered in the development of a rulemaking plan, "Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements," which was provided to the Commission in SECY-02-0196 (November 1, 2002). The rulemaking plan called for revisions to the exemptions from licensing in Part 30, some general licenses in Part 31, and the requirements for exempt distribution in Part 32. The staff proposed that the results of the systematic reevaluation of the exemptions for the regulation of source material would be addressed in a separate rulemaking addressed in SECY-01-0072, "Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22, 'General License,'" April 25, 2001. The staff is currently compiling supplemental information to SECY-01-0072, as directed by the Commission. The SRM on SECY-02-0196 was issued on November 17, 2003. The Commission directed the staff to proceed with rulemaking, but disapproved the inclusion of certain issues in the rulemaking. About half the issues approved by the Commission are in this rulemaking. The proposed rule was published on January 4, 2006 (71 FR 275). The others will be in another rulemaking.

Project Considerations: The Exemptions Working Group evaluated the requirements related to exemptions and certain generally licensed devices, identified a number of issues for consideration in rulemaking, and developed recommendations for improving the regulatory framework for both the Part 30 exemptions from licensing for byproduct material and the Part 40 exemptions for source material. Recommendations for Part 40 were coordinated with the Part 40 Rulemaking Working Group.

The working group includes members from NMSS, OGC, OSTP, RES, OE, ADM, OIS, OCFO, and the Agreement States (CO).

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Proposed rule to EDO	May 2005	August 2005	August 2005	NMSS/IMNS/RGB
Proposed rule published			January 2006	NMSS/IMNS/RGB
Final rule to EDO	January 2007			NMSS/IMNS/RGB

SA-16 Safety Strategic Plan Goal

Implementation Activity: Materials Licensing Guidance Consolidation and Revision (NMSS/IMNS/RGB)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste related activities to protect public health, safety, and the environment.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 9: Foster innovation at the NRC to improve systematically the NRC's regulatory programs.

Primary Priority: High

Secondary Priority: High

Description of Activity:

In FY 01 the Division of Industrial and Medical Nuclear Safety (IMNS) completed the first phase of licensing guidance consolidation with the final publication of 20 volumes of "Consolidated Guidance about Materials Licenses" (NUREG-1556). Since that time, NUREG-1556, Volumes 1, 3, and 9 have been revised.

The remaining volumes of NUREG-1556 will be reviewed periodically and revised, if needed. The recommendations from the Phase II report (issued August 2001) from the Multiphase Review of the Byproduct Materials Program activity will be incorporated. (Phase II is a broad review of the entire materials program, while Phase I focused on lessons learned from the overexposure events at the Mallinckrodt facility and a radio-pharmacy.) The future revisions will integrate risk information contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems."

The following volumes of NUREG-1556 are scheduled for completion, review, or revision in FY07 and FY08.

Vol. 2	Program-Specific Guidance About Radiography Licenses
Vol. 8	Exempt Distribution Licenses

Project Considerations: If other than administrative revisions are needed, the NUREG will be published for public comment. If a new rule or amendment is promulgated, guidance will be developed or revised.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Complete Vol. 2, Revision 1	Fall 2003	Fall 2007		NMSS/IMNS/RGB
Complete Vol. 8, Revision 1 (draft)	Summer 2005	Fall 2007		NMSS/IMNS/RGB
Complete Vol. 20, Revision 1	Spring 2005	Summer 2007		NMSS/IMNS/RGB

SA-17 Safety Strategic Plan Goal

Implementation Activity: Implementation of Part 70 revision (NMSS/FCSS/TSG)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste-related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Primary Priority: Medium

Secondary Priority: Medium

On September 18, 2000 (65 FR 56211), the Commission published a final rule (Part 70) amending its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a "Petition for Rulemaking," PRM-70-7, submitted by the Nuclear Energy Institute, which was published on November 26, 1996 (61 FR 60057). The majority of the modifications to Part 70 are included in a new Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." These modifications were made to increase confidence in the margin of safety at the facilities affected by the rule, while reducing unnecessary regulatory burden, where appropriate.

In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach by requiring licensees to (1) perform an integrated safety analysis (ISA) to identify significant potential accidents at the facility and the items relied on for safety; and (2) implement measures to ensure that the items relied on for safety are reliable and available to perform their functions when needed.

In December 2001, NMSS/FCSS staff, along with the Risk Task Group and Part 70 stakeholders, finalized a standard review plan to implement the requirements of Subpart H. NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," complements 10 CFR Part 70 by identifying the specific information to be submitted by an applicant and evaluated by the staff. This guidance document, which was published in March 2002, will assist the licensees in conducting ISAs and the staff in reviewing ISA documentation. In September 2003, July 2004, and February 2005, FCSS held ISA workshops with industry and the public to discuss implementation of the Part 70 Subpart H requirements, obtain industry comments and feedback, and identify areas that

needed additional study and/or guidance. From March to June 2004, FCSS also held six internal staff workshops to discuss ISA requirements, implementation, and issues. As issues have been raised and addressed, the NRC has developed draft ISGs to further guide and document its approach to these issues. Interim staff guidance is being prepared for nine areas. NRC provided the nine ISGs to industry since the summer of 2004. Seven of these have been issued in final form (ISGs 1, 3, 4, 5, 8, and 9); two (ISGs 6 and 7) – dealing with meeting the October 1, 2004 deadline -- have been cancelled due to a lack of need; and one (ISG 2) is under revision. The staff held a workshop an additional workshop in August 2005, to discuss issues related to inspection of the ISA implementation. The staff discussed other implementation issues with stakeholders as part of the Fuel Cycle Information Exchange (FCIX) 2006, held on August 30 and 31, 2006.

The staff began conducting ISA summary reviews in FY 2004 for individual amendment requests, for certain existing and new processes, and for a new centrifuge enrichment license application in FY 2004. To date, all licensees required to submit an ISA summary have done so. All ISA Summaries were submitted by the regulatory due date of October 18, 2004 or as part of a new license application. The staff reviews of these ISA summaries has shown that each licensee has used varying approaches to satisfy the requirements of 10 CFR 70.61. The submittals were accepted based on the acceptance criteria identified in NUREG-1520; however, all of the ISA submittals have required formal Requests for Additional Information (RAIs) as well as site visits and verbal communication with the licensees to clarify the ISA methodologies used and means of implementation. These reviews will continue through FY 2007.

The following important issues remain for completing the transition of ISAs to a more risk-informed approach: the treatment of dependent failures, human reliability, the treatment of uncertainty, and the aggregation or assembly of the scenarios into overall facility or system measures of risk.

As more issues come to light, the NRC will continue to revise or augment the ISGs to provide clarification and support consistency in the reviews of the ISA summaries. As experience is gained and consensus developed on the ISGs, consideration will be given to modifying NUREG-1520 to be more risk-informed and, therefore, more effective and efficient. It is assumed that now that these initial models have been developed and the data requirements are better defined, a greater amount of objective data will become available in the future. For example, operational and maintenance data from these systems can be fed back into the models to replace or validate initial assumptions. Additionally, the availability of this data will allow the uncertainties associated with the systems to be better quantified. In this way, the ISA process will achieve its true objective: to accurately reflect the facility processes and hazards and ensure those hazards are appropriately managed and controlled.

Additionally, efforts have been made to risk-inform the inspection guidance for Part 70 licensees. Inspection procedures for Category I and III facilities are being upgraded to reduce inspection duplication and allocate time spent on each procedure based on risk significance. The procedures focus on risk-significant activities for headquarters and regional inspectors and provide guidance for inspectors on the appropriate risk-significant items to evaluate in a licensee's program. As of July 2006, 16 procedures have been revised and six of these have been approved and issued.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Finalize standard review plan for 10 CFR Part 70, Subpart H			December 2001	NMSS/FCSS/TSG
Publish standard review plan for 10 CFR Part 70, Subpart H			March 2002	NMSS/FCSS/TSG
Initiate technical reviews of fuel cycle licensees' ISA summaries	as received from licensees		September 2005	NMSS/FCSS/TSS

SA-18 Safety Strategic Plan Goal

Implementation Activity: Develop methods for assessing performance of steam generator tubes and other reactor coolant system (RCS) components during severe accidents (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 2: Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

The integrity of steam generator (SG) tubes in pressurized-water reactors is a key consideration in maintaining plant safety during design basis and severe accidents. Design basis accident tube ruptures can result in offsite radioactive releases that could require emergency response and approach the limits of the 10 CFR Part 100 siting requirements. Severe accident tube ruptures, in which a tube rupture either initiates the accident or occurs during the accident, can result in bypass of the containment structure and subsequent offsite health consequences. Thus methods to assess the integrity of tubes during normal operations and to repair deficient tubes are important elements of the industry's safety programs and the staff's regulatory activities.

The staff currently is working to develop methods and tools to address steam generator tube integrity during postulated severe accidents in pressurized-water reactors. The plan for the work has three parts: probabilistic risk analysis, thermal hydraulics, and structural behavior of steam generator tubes and other reactor coolant system components. (This work uses materials and thermal-hydraulic analyses that DFERR and DRASP, respectively, have been doing for several years). DRASP has now incorporated these analyses and their results into a risk-informed prototype method that will enable quantification of the frequency of containment bypass events from steam generator tube failures. Future plans include further development of the prototype method to include improved consideration of human actions, consideration of initial conditions other than full-power operation, consideration of initiators other than internal events, and consideration of other plant designs (the initial prototype method was developed using a Westinghouse 4-loop plant).

Primary Priority: High

Secondary Priority: High

Project Considerations: DRAA staff has applied the prototype method to a sample plant to calculate the frequency of containment bypass events due to SG failures induced by severe accident conditions at that plant. The staff is evaluating the prototype model and the results of its application to the sample plant to determine the nature and extent of expansions and improvements needed in the model. One

area identified as needing improvement is in the area of human reliability. Also, thermal-hydraulic assessments have identified a sensitivity to certain parameters. These parameters are being studied and uncertainties are being investigated. Depending upon the results of these assessments, in conjunction with consideration of the resources available for this effort, the staff will determine the scope and schedule of remainder of this project. The schedule (below) is based on performing the aforementioned work, namely evaluating the parameter and uncertainty assessments and enhancing the human reliability analysis used in the PRA assessments.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Develop logic framework for improved PRA model of scenarios identified as risk-significant, including the effects of operator actions	April 2004		April 2004	RES/DRASP
Using results of the preceding major milestone, identify scenarios, calculate the frequency of containment bypass events at an example plant, make indicated model improvements, and document the improved methods and results	August 2004		May 2005	RES/DRASP
Extend, generalize, and document the SAI-SGTR risk analysis method	February 2004	December 2007		RES/DRASP
Final reports	February 2004	December 2007		RES/DRASP

SA-19 Safety Strategic Plan Goal

Implementation Activity: Risk-Informing the Standard Review Plan (SRP) - Improving New Reactor Review Efficiency Through Application of Risk Insights (NRR/ADRA/DRA)

Primary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste-related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Primary Priority: Medium

Secondary Priority: High

The purpose of this effort is to support an initiative in NRR/ADRA/DNRL to improve the use of the Standard Review Plan (NUREG-0800) in reviewing new reactor license applications. The DNRL initiative is to develop a web-based desk-top guide that will capture review experience (“lessons learned”), link SRP chapters and referenced documents, and thereby improve the efficiency and effectiveness of the review.

DRA will provide risk insights for each new reactor type for inclusion in the DNRL web-based desk-top guide. Guidance and high-level training for applying these insights will also be developed. This effort will provide NRR (NRO) technical staff with a basic framework for applying risk insights to the review of new reactor license applications for those areas of the SRP that are amenable to being risk-informed.

The resulting framework and procedure should enhance NRR staff's efficiency in performing reviews using the SRP guidance. Specific objectives include the following:

- Ensure the effective review of safety analysis reports to provide reasonable assurance that public health and safety are maintained. An effective review is one that would identify, should they exist, any non-conforming aspects or other issues that would be inimical to public health and safety.
- Facilitate the efficient review of safety analysis reports through use of a graded approach to the depth and level of detail of the review. A graded approach is one in which the level of resources applied to a given review is commensurate with the importance of the topic being reviewed to assuring public health and safety.

While the SRP provides a useful list of areas to review, it does not necessarily provide any indication of how important a given area is to assuring public health and safety. Given that review of an applicant's information will never be a complete design verification of every detail, and given limited resources and a finite schedule to perform the review, reviewers of necessity focus on those areas that, in their judgment, are important to providing this assurance. Risk techniques and insights provide valuable input to a reviewer in determining the scope and level of detail to be reviewed in a certain area.

DRA will provide a framework and process for supplying risk insights from new reactor PRA submittals to be included in the "risk insights" portion of the web-based, SRP desk guide under development by DNRL. The risk insights will be provided for those SRP sections for which risk insights exist for a given reactor type.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Form technical team to identify possible approaches to risk-inform the SRP to enhance new reactor review efficiency.	February 2006		February 2006	NRR/DRA (M. Laur, x3719)
Provide ESBWR risk insights to DNRL to support revised SRP pilot effort to develop "desk guides" to focus new reactor reviews.	April 2006		April 2006	NRR/DRA/APLB (N. Saltos, x1072)
Develop options to risk-inform the SRP, including pros and cons of each.	May 2006		May 2006	NRR/DRA (M. Laur, x3719)
Present options to Director, ADRA, and obtain concurrence to proceed with team recommendation.	June 2006		June 2006	NRR/DRA/APLA (S. Laur, x2889)

Identify SRP sections amenable to being risk-informed.	October 2006			NRR/DRA/APLA (T. Hilsmeier, x6788)
Develop a template for use by DRA to transmit reactor type-specific risk insights to DNRL for inclusion in the web-based, SRP desk guide for the SRP sections identified in milestone # 5.-425	January 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Meet with DNRL and present proposed template and process; incorporate feedback and comments.-425	May 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Develop guidance document that describes how DRA will transfer plant-specific PRA information to DNRL for the applicable SRP sections.	June 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Develop 5 or 6 sample templates using AP 1000 PRA. Present to senior management and use as examples for training.	July 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Develop and conduct DRA training for technical reviewers who will be reviewing new reactor PRA submittals and providing risk information to DNRL for inclusion on the web-based, SRP desk guide.	July 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Conduct training seminars for all technical reviewers who will be using the risk insights included in the web-based, SRP desk guide.	August 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Provide EPR risk insights to DNRL in accordance with the guidance document developed in step 8.	December 2007			NRR/DRA/APLA (T. Hilsmeier, x6788)
Provide PRA insights for each additional reactor type as they become available.	TBD			NRR/DRA/APLA (T. Hilsmeier, x6788)

CHAPTER 2. EFFECTIVENESS

Goal: Ensure That NRC Actions Are Effective, Efficient, Realistic, and Timely

Strategic Outcome: No significant licensing or regulatory impediments to the safe and beneficial uses of radioactive materials.

2.1 Introduction

Over the next several years, the NRC anticipates a significant increase in agency workload. In particular, the workload is likely to include licensing requests of unprecedented complexity. Security demands are becoming more complex, requiring diverse professional expertise and close coordination with other Federal, State, and local agencies. Increases in both the frequency and the extent of stakeholder involvement in the NRC's regulatory processes are expected as the agency works to improve openness.

These and other challenges are coming at a time when initiatives such as the Government Performance and Results Act are challenging Federal agencies to become more effective and efficient and to justify their budget requests with demonstrated program results. The drive to improve performance in Government, coupled with increasing demands on the NRC's finite resources, clearly indicates a need for the agency to become more effective, efficient, realistic, and timely in its regulatory activities.

Effectiveness means achieving the desired outcome from a program, process, or activity. The concept of effectiveness applies to all levels of the agency, from individual actions to programs and agency-wide initiatives.

Efficiency refers to productivity, quality, and cost characteristics that together define how economically an activity or process is performed. The NRC recognizes that the efficiency of the agency's regulatory processes is important to the regulated community and other stakeholders, including Federal, State, and local agencies, and to the public. Efficient regulatory processes help the NRC to meet stakeholder expectations regarding timely, accurate, and responsible agency actions. While the NRC will never compromise safety for the sake of increased efficiency, the agency works to improve the efficiency of its regulatory processes whenever practicable.

Timeliness, a key aspect of efficiency, means acting within a predictable time period and without unnecessary delays. NRC actions should be timely to support the agency's strategic objective of enabling the safe, beneficial use of radioactive materials. The timeliness of agency actions is key to providing a stable, reliable, and responsive regulatory environment. The agency has established timeliness goals for many of its regulatory activities and regularly tracks its performance in meeting these goals.

Throughout the regulatory processes, the NRC seeks to impose only those requirements that are necessary to achieve the agency's mission. NRC regulations were established using the "defense-in-depth" principles and conservative practices that, in some cases, have led to requirements that may exceed what is necessary to reasonably ensure the protection of public health and safety and the environment. Advances in risk analysis and scientific understanding, as well as lessons learned through operating experience, are used to help the agency to focus on the most significant safety requirements and, in certain instances, to avoid unnecessary conservatism that offers little safety benefit.

The NRC believes that efforts to improve efficiency, timeliness, and realism are congruent with the agency's safety and security goals. In fact, initiatives related to this goal should serve to sharpen the agency's focus on safety and security and ensure that available resources are optimally directed toward the NRC's mission.

2.2 Effectiveness Strategies

The NRC will employ the following strategies to ensure that its actions are effective, efficient, realistic, and timely:

- (1) Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.
- (2) Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements
- (3) Use performance-based regulation to minimize unnecessarily prescriptive requirements.
- (4) Use realistically conservative, safety-focused research programs to resolve safety-related issues.
- (5) Enhance cooperation with Federal, State, and Tribal governments and international counterparts.
- (6) Minimize unnecessary regulatory or jurisdictional overlap.
- (7) Anticipate challenges and respond quickly to changes in the regulatory and technical environment.
- (8) Make timely regulatory decisions.

- (9) Foster innovation at the NRC to improve systematically the NRC's regulatory programs.

2.3 Current Effectiveness Initiatives and Activities

- EF-1 Creating a risk-informed environment
- EF-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees
- EF-3 Develop and maintain analytical tools for staff risk applications
- EF-4 Develop the technical basis for the PTS rule
- EF-5 Develop methods for assessing steam generator performance during severe accidents (renamed SA-18)
- EF-6 Develop structure for new plant licensing
- EF-7 Develop and apply methods for assessing fire safety in nuclear facilities
- EF-8 Develop a coherence program for reactor safety (incorporated into EF-6)
- EF-9 Establish guidance for risk-informed regulation: development of HRA
- EF-10 PRA review of advanced reactor applications
- EF-11 Develop a framework for incorporating risk information in the NMSS regulatory process
- EF-12 Develop risk guidelines for the materials and waste areas (completed)
- EF-13 Systematic decisionmaking process development (completed)
- EF-14 Probabilistic risk assessment of dry cask storage systems
- EF-15 Interagency Jurisdictional Working Group evaluating the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium

and/or thorium

- EF-16 Multiphase review of the Byproduct Materials Program (completed)
- EF-17 Revise Part 36: Requirements for Panoramic Irradiators (PRM-36-01)
- EF-18 Develop an alternative risk-informed approach to special treatment requirements in Part 50 to vary the treatment applied to structures, systems, and components (SSCs) on the basis of their safety significance using a risk-informed categorization method
- EF-19 Develop a plan for making a risk-informed, performance-based revision to 10 CFR Part 50
- EF-20 Reactor Oversight Process (ROP) support (formerly SA-2)
- EF-21 SPAR Model Development Program (formerly SA-6)
- EF-22 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”) (formerly SA-8)
- EF-23 Risk-informing of Standard Review Plans For Independent Spent Fuel Storage Installations and Packages

These initiatives and activities are described in detail on the following pages. The descriptions include applicable project considerations, such as priority, schedule, and milestones, and special considerations (e.g., training, stakeholder communications, external dependencies).

EF-1 Effectiveness Strategic Plan Goal

Implementation Activity: Creating a risk-informed environment (RIE) (NRR/ADRA/DRA)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 7: Anticipate challenges and respond quickly to changes in the regulatory and technical environment.

Strategy 8: Make timely regulatory decisions.

Primary Priority: Medium

Secondary Priority: Medium

In its Probabilistic Risk Assessment (PRA) Policy Statement (60 FR 42622; August 16, 1995), the Commission provided high-level guidance to increase the use of PRA technology while complementing regulatory decision-making methods. The staff was directed to implement a framework that places emphasis on the areas of highest risk while reducing focus on areas of lower risk, thereby conserving resources and reducing unnecessary regulatory burden.

In accomplishing this objective, the Office of Nuclear Reactor Regulation (NRR) identified the need to broaden the staff's knowledge and acceptance of risk in its day-to-day activities. In response, NRR began a risk-informed environment (RIE) initiative in 2001. Since then, the initiative has produced two major reports on the current environment and ways to improve it, as well as a plan to risk-inform the NRR environment, defining strategies keyed to specific functional areas and a plan of action for implementing each strategy. The activities proposed in the plan have yet to be implemented, as a result of organizational changes and resource limitations.

Several developments (such as the October 2005 NRR reorganization and development of risk communication guidance) have contributed to improvement of the risk-informed environment. However, the results of the 2005 Office of the Inspector General (OIG) NRC Safety Culture and Climate Survey, issued in February 2006, identified several areas for improvement in the risk-informed environment associated with the reactor program. The survey identified the need for individual employee priority on risk-informed regulation, improved perception of risk-informed regulation's contribution to regulatory effectiveness, and increased management attention to processes, tools, and training that enable implementation of risk-informed regulation.

A team of staff in NRR has developed an action plan to further NRR's progress toward meeting the Commission's goals for establishing a risk-informed framework, complement the October 2005 NRR reorganization, and help address some of the negative conclusions of the 2005 OIG survey. The staff plans to take action in five areas by the end of the 2007 fiscal year.

Selected Major Milestones and Schedule				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
New units on risk-informed regulation in office qualification plans	January 2006			NRR/DRA/APLB
Increased risk knowledge among first-line supervisors	October 2007			NRR/DRA/APLB
Formal training of all NRR technical staff	October 2007			NRR/DRA/APLB
Informal web-based training	April 2007			NRR/DRA/APLB
Web-based forum of expertise	January 2006			NRR/DRA/APLB
Assessment of initiative's effectiveness	October 2004	April 2008		NRR/DRA/APLB

EF-2 Effectiveness Strategic Plan Goal

Implementation Activity: Develop standards and related guidance for appropriate PRA quality and the application of risk-informed, performance-based regulation in conjunction with national standards committees and industry organizations (RES/DRASP, NRR/ADRA/DRA)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 2: Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: High

Secondary Priority: Medium

The increased use of probabilistic risk assessments (PRAs) in the regulatory decisionmaking process of the NRC 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 PRAs developed by NRC staff to analyze specific technical issues or to support Commission decisions. To this end and to streamline staff review of license applications, professional societies, the industry, and the staff undertook initiatives to establish consensus standards and guidance on the use of PRA in regulatory decisionmaking.

The American Society of Mechanical Engineers (ASME), the Nuclear Energy Institute (NEI), and the American Nuclear Society (ANS) each have the following responsibilities:

ASME:

- PRA standard for a Level 1 analysis (i.e., estimation of core damage frequency (CDF)) and a limited Level 2 analysis [i.e., estimation of large early release frequency (LERF)] covering internal events (transients, loss-of-coolant accidents, and internal flood) at full power

NEI:

- PRA peer review guidance on internal events at full power (Level 1 and simplified Level 2)
- Self-assessment guidance for determining the significance of differences between the peer review criteria and the ASME PRA standard

ANS:

- external hazards
- low-power and shutdown (LP/SD) conditions
- internal fires

Recently, the staff has participated in discussions with ASME and ANS on the development of an integrated PRA quality standard. This integrated standard would be issued jointly by ASME and ANS and includes the relevant PRA areas noted above. An integrated standard is expected to be more effective and efficient than several stand alone standards because of consistency in the approach and style to develop the standard and incorporation of subsequent revisions to the standard. The staff will continue to work with ASME and ANS in determining the need for an integrated standard.

In parallel, the staff is also working with the National Fire Protection Association (NFPA) to develop standards for fire protection risk analysis. (See SA-11.)

The NRC staff is working with the ASME and other organizations to incorporate risk insights into codes and standards applicable to various activities at nuclear power plants. For example, the ASME is updating the *Code for Operation and Maintenance of Nuclear Power Plants* and applicable code cases to allow the use of risk insights in the inservice testing of pumps and valves. ASME is also developing code cases under Section XI of the *Boiler & Pressure Vessel Code* to apply risk insights in the inservice inspection of structures, systems, and components. The NRC staff has developed regulatory guides to document the acceptance of some of the risk-informed code cases as well as a regulatory guide to list the code cases that the staff has found to be unacceptable. These regulatory guides were finalized and published in June 2003.

It is also expected that licensees will use the PRA standards and industry guidance to help demonstrate and document the adequacy of their PRAs for a variety of risk-informed regulatory applications. Therefore, the staff position on the adequacy of the standards and industry guidance to support regulatory applications is documented in a regulatory guide and associated staff guidance in a standard review plan. Such documentation will indicate in which areas staff review can be minimized and where additional review may be expected. To accomplish this objective, the staff has developed RG 1.200 to provide an approach for assessing the adequacy of PRA results used in

support of regulatory applications and an accompanying standard review plan (SRP) chapter. RG 1.200 and the associated SRP chapter are intended to support all risk-informed activities. The staff's position on each PRA standard and industry guidance is provided in the appendices.

In an SRM on COMNJD-03-0002, "Stabilizing the PRA Quality Expectations and Requirements," dated December 18, 2003, the Commission approved implementation of a phased approach to achieving an appropriate quality for PRAs for NRC's risk-informed regulatory decisionmaking. The SRM directed the staff to engage stakeholders and develop an action plan that defines a practical strategy for the implementation of the phased approach to PRA quality so that industry would move in the direction of better, more complete PRAs; efficiencies would be introduced into the staff's review of risk-informed applications; and staff would be allowed to establish PRA quality expectations for 10 CFR 50.46 and 10 CFR 50.69 that may be less stringent than required by the March 31, 2003, SRMs.

The SRM specifies four phases for the NRC staff's efforts. The phase is determined by the availability of the PRA guidance documents (e.g., quality standards, industry guides, regulatory guides) needed to generate the results/decision required for an application. For most applications, the effort is now in Phase 1. Phase 2 will be achieved in stages as application quality needs are identified and guidance documents become available for specific application types. For Phase 2, the scope of the PRA required is a function of the decision to be made (e.g., 50.69, AOT extensions). To complete Phase 3 the staff will produce (by December 31, 2008) an overall guidance document regarding PRA technical adequacy for risk-informed applications. Phase 4 calls for the industry to have full-scope, full-quantification, full-uncertainty analysis PRAs that will be reviewed and approved by the NRC. The Commission did not set a date for implementation of Phase 4.

The staff developed an action plan and provided it to the Commission in July 2004 as SECY-04-0118. The Commission approved the plan in an SRM dated October 6, 2004.

Project Considerations: The regulatory guide (1.200) will be evaluated as part of the staff's plan to implement a phased approach to PRA quality. The schedule is set by the various standards and industry organizations and is dependent upon the standards committees and industry organizations meeting their schedules. If ASME and ANS proceed with development of an integrated standard, the staff will revise the milestones and schedule to reflect that approach. (This project is closely tied to almost every other activity related to reactor safety. NRR and RES staff are working closely together on this project and will continue to coordinate with the other activities, as needed.)

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Pilot applications of RG1.200 for trial use	December 2004	March 2005	March 2005	NRR/DRA/APLA (G. Parry, x1464 D. Harrison, x3587)
Draft Guide (DG) 1138, Appendix C to RG 1.200 (staff position on PRA standards issued by ANS on external hazards)	December 2003	August 2004	August 2004	RES/DRASP
Update to ASME PRA standard: Addendum B	January 2005	June 2005	July 2005	N/A (ASME)
Update to NEI peer review guidance and self-assessment guidance (NEI schedule is based on ASME schedule for Addendum B)	April 2005	September 2005	May 2006	N/A (NEI)
Issue RG 1.200, Rev. 1 (Appendices A and B) ¹	December 2005	December 2006		RES/DRASP
Update to ANS external events PRA standard, Revision 1	June 2005	June 2007		N/A (ANS)
Update DG-1138, Appendix C to RG 1.200 (staff position on ANS PRA standard on external events) ¹	December 2005	September 2007	Canceled*	RES/DRASP
Final PRA standards issued by ANS on LP/SD	June 2002	June 2007		N/A (ANS)
Appendix D ¹ (staff position on LP/SD standards issued by ANS) - for comment	December 2004	December 2007	Canceled*	RES/DRASP
Final internal fire standard issued by ANS	June 2006	June 2007		N/A (ANS)
Appendix E ¹ (staff position on internal fire PRA standards issued by ANS)	December 2005	June 2007	Canceled*	RES/DRASP
Issue draft RG 1.200, Rev. #2 ¹ (Appendices A, B, C, D, and E)	June 2008			RES/DRASP
Issue RG 1.200, Rev. #2 ¹ (Appendices A, B, C, D, and E)	June 2008	December 2008		RES/DRASP

Implement PRA quality, Phase 3 ²	December 2008			NRR/DRA/APLA (G. Parry, x1464) RES/DRASP
NUREG on treatment of uncertainties and use of alternate methods (draft for public review and comment)	October 2005	December 2006		RES/DRASP

* These appendices will be issued as part of issuing draft Rev. 2 to RG 1.200

¹Recognizing that control of these projects rests with the standards committees, milestones have been established by, and can be revised by, these organizations.

EF-3 Effectiveness Strategic Plan Goal

Implementation Activity: **Develop and maintain analytical tools for staff risk applications (RES/DRASP)**

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decision-making.

Primary Priority: High

Secondary Priority: Medium

The NRC has developed and maintains the SAPHIRE (Systems Analysis Program for Hands-on Integrated Reliability Evaluation) computer code for performing probabilistic risk analyses (PRAs). SAPHIRE offers state-of-the-art capability for assessing the risk associated with core damage frequency (Level 1 PRA) and the risk from containment performance and radioactive releases (Level 2 PRA). SAPHIRE supports the agency's risk-informed activities, which include the SPAR model development plan, the risk assessment standardization project, the Significance Determination Process, risk-informing Part 50, vulnerability assessment, advanced reactors, operational experience, generic issues, and regulatory backfit. The NRC's risk-informed decision-making process necessitates continuous support of SAPHIRE. Therefore, the staff plans to continue maintaining, improving, and providing user support for the SAPHIRE code and its user-friendly interface, the Graphical Evaluation Module (GEM).

EF-4 Effectiveness Strategic Plan Goal

Implementation Activity: Develop the technical basis to revise the PTS rule. (RES/DFERR)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

In 1986, the NRC established the pressurized thermal shock rule (10 CFR 50.61) in response to an issue concerning the integrity of embrittled reactor pressure vessels in pressurized-water reactors. The NRC staff is now reevaluating the technical basis of this rule in light of the results of subsequent extensive research on key technical issues underlying the rule. Analyses performed as part of this research suggest that the agency may be able to reduce unnecessary conservatism in the rule while still maintaining safety.

The staff's approach to reevaluating the screening criteria that 10 CFR 50.61 prescribes for reactor pressure vessel material characteristics is described in SECY-00-0140, "Reevaluation of the Pressurized Thermal Shock Rule (10 CFR 50.61) Screening Criterion," dated June 23, 2000, and subsequent periodic status reports (SECY-01-0045, SECY-01-0185, and SECY-02-0092, dated March 16, 2001, October 5, 2001, and May 30, 2002, respectively). In March of 2005 ACRS provided a favorable review of RES reports detailing the technical basis for PTS rule revision, and in June of 2005 these draft reports were issued to NRR for review. These reports integrated sequence frequency, thermal-hydraulic, and fracture mechanics analyses (using the probabilistic fracture mechanics code FAVOR) to calculate the frequency of vessel failure due to PTS. This report presented the bases for possible changes to the PTS rule. NRR completed its initial review of the RES reports in September 2005 and in October 2005 initiated rulemaking. Several outstanding technical issues have been identified by NRR, and RES is resolving these while the rulemaking process proceeds. It is anticipated that the technical basis reports will be finalized in December 2006.

Primary Priority: High

Secondary Priority: Medium

Project Considerations: None.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Final report with detailed description of PRA analysis methods and results for peer review	October 2003		December 2004	RES/DRASP
Peer review of the final report on recommended changes in PTS screening criteria	June 2003	November 2004	December 2004	RES/DFERR
Final report on recommended changes in PTS screening criteria (to NRR)	September 2003	December 2006		RES/DFERR

EF-6 Effectiveness Strategic Plan Goal

Implementation Activity: Develop structure for new plant licensing (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Strategy 1: Provide accurate and timely information to the public about the uses of and risks associated with radioactive materials.

Primary Priority: High

Secondary Priority: Medium

The staff has developed and implemented a plan to develop a regulatory structure for new plant licensing. The objective is to provide an approach for the staff to enhance the effectiveness and efficiency of new plant licensing in the longer term. It will provide the technical basis for future rulemaking for technology-neutral regulations for new plant licensing, i.e., for a new Part 53. It is to be technology-neutral to accommodate different reactor technologies, risk-informed to identify the more likely safety issues and gauge their significance, and performance-based to provide flexibility, and will include defense-in-depth to address uncertainties.

The staff is developing a technology-neutral framework/guideline for the regulatory structure which will also include (1) the content of a set of technology-neutral requirements and (2) guidance for applying the framework on a technology-specific basis.

The staff has held public meetings, internal management meetings, and a public workshop, and has briefed the ACRS on the staff's progress. The framework structure is a top-down approach to translating the mission of the Atomic Energy Act (protecting the public health and safety) into a set of technology-neutral requirements. Criteria and guidance are included for:

- safety, security, and preparedness expectations
- risk expectations
- design, construction, and operational expectations
- treatment of uncertainties

- performance-based concepts
- PRA technical acceptability

As the guidance and criteria are developed, policy and technical issues will be identified for Commission consideration. The current issues include level of safety, treatment of integrated risk for multiple reactors at a single site, and containment versus confinement. Preliminary initial guidance has been developed for each of these issues. Initial feedback from stakeholders has been positive. The ACRS considers "the completion of this effort to be essential for the efficient and effective certification of non-LWR designs . . . the staff has a strategic approach and is articulating and addressing difficult technical and policy issues We look forward to continued discussion of the staff's progress."

A staff requirements memorandum (SRM) was issued on May 9, 2005 for the Commission meeting held on Tuesday, April 5, 2005, on the subject of Briefing on RES Programs, Performance, and Plans. One item in this SRM states: "RES staff should work with NRR to develop a formal program plan to make a risk-informed and performance-based revision to 10 CFR 50 (Part 50), including revisions to the applicable Regulatory Guides, Standard Review Plans, or other guidance documents." The plan proposed by the staff involves creating a completely new risk-informed and performance-based revision to 10 CFR Part 50 that is technology-neutral. This new Part 53 is a continuation and advancement of the work described above. The development of this new Part 53 will integrate safety, security, and preparedness. This approach will ensure that the reactor regulations, and staff processes and programs, are built on a unified safety concept and are properly integrated so that they complement one another.

In a September 14, 2005, SRM (ML052570437) in response to SECY-05-0130, "Policy Issues Related to New Plant Licensing and Status of the Technology-Neutral Framework for New Plant Licensing," the Commission subsequently directed the staff to develop in an expeditious fashion an advance notice of proposed rulemaking (ANPR) to consider the spectrum of issues relating to risk-informing the reactor regulations. The Commission further directed the staff to incorporate into the ANPR the formal program to risk-inform Part 50, as well as other related risk-informed efforts, and to integrate safety, security, and preparedness throughout the effort.

On September 21, 2005, SRM (ML052640492) in response to SECY-05-0138, "Risk-Informed and Performance-Based Alternatives to the Single-Failure Criterion," the Commission again directed the staff to expedite development of an ANPR on development of risk-informed and performance-based alternatives to the single failure criterion, and to integrate safety, security, and preparedness throughout the effort. This is consistent with the Commission direction provided in the SRM to SECY-05-0130.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Hold public workshop to engage stakeholders and solicit input	March 2005		March 2005	RES/DRASP
Issue paper to Commission with staff recommendations on policy and technical issues	July 2005		July 2005	RES/DRASP
Publish ANPR on risk-informed performance-based revision to 10 CFR Part 50	April 2006		May 2006	NRR/ADRA
Place current working draft of framework on RuleForum Web site to supplement the ANPR	April 2006		April 2006	RES/NRR/NSIR
Complete final draft of framework for public review and comment	December 2005	December 2006	July 2006	RES/DRASP
Paper to Commission on policy issues on level of safety and integrated risk, path forward on containment functional performance requirements and definition of defense-in-depth, and stakeholders' views on the ANPR	October 2006	May 2007		NRR/RES/NSIR
Issue final framework	June 2005	May 2007		RES/DRASP

EF-7 Effectiveness Strategic Plan Goal

Implementation Activity: **Develop and apply methods for assessing fire safety in nuclear facilities (RES/DRASP)**

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 4: Use realistic, conservative safety-related research programs to resolve safety-related issues.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: High

Secondary Priority: Medium

The development of risk-informed, performance-based fire standards and regulations requires a sound understanding of fire and its contribution to power plant risk. A fire research program has been developed and is being implemented to address the complex issues associated with fire risk and to support risk-informed changes to these standards and regulations. Also, RES is performing specialized testing to support other NRC program offices.

The staff worked with the National Fire Protection Association (NFPA) to develop a performance-based, risk-informed fire protection standard (NFPA 805) for nuclear power plants. NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," was issued in January 2001 and serves as the basis for the new rule, 10 CFR 50.48(c). RES and EPRI are providing the technical basis for this implementation by developing state-of-art fire PRA methods, tools, and data, as documented in final NUREG/CR-6850 (EPRI 10011989), "EPRI/NRC-RES Fire PRA Methodology for Nuclear Power Facilities," and providing verification and validation (V&V) of a range of fire models.

The ACRS provided RES a very favorable letter on NUREG/CR-6850. Also, RES and EPRI held a highly successful 3-day public workshop in June 2005 on this methodology. Due to stakeholder interest, RES and EPRI have conducted a second fire PRA workshop at NRC headquarters in May

2006. Industry needs this fire PRA methodology and the fire model V&V tools to justify changes to fire protection programs and NRC needs them to assess those analyses. The fire model V&V project is also a joint research program being conducted with EPRI. The draft NUREG-1824 was released for public comment in January 2006. The final report will be issued in January 2007. In addition, RES has completed guidance based upon NUREG/CR-6850 to assist agency fire protection and risk engineers in reviewing these risk-informed analyses.

The fire risk standard is a part of the Commission's phased approach to PRA quality (SECY-04-0118), and will support implementation of the risk-informed, performance-based rule endorsing NFPA 805. This standard developed under the auspices of the American Nuclear Society (ANS) provides categories of fire risk assessment (FRA) quality which will be relevant to application of FRA. RES is providing support to the Committee for drafting and reviewing the standard. The standard was issued by ANS for public review and comment in April 2006; this public comment period closes in August. Once the standard is completed, RES will participate in the review for purposes of endorsement in Regulatory Guide 1.200.

RES is supporting the NRR Circuit Analysis Resolution Program. NEI has completed a series of fire tests which provided insights on electrical cable performance and subsequent failures during a thermal insult. RES provided additional instrumentation to supplement the NEI data. EPRI assembled and completed the work of an expert panel to evaluate the test results. RES provided a cable expert to support this EPRI expert elicitation project. This work was published by EPRI in May 2002 as "Spurious Actuation of Electrical Circuits Due to Cable Fires" (EPRI report 1006961). This testing and analysis, a facilitated workshop consisting of industry and staff, and a well-established RES program in this area enabled RES to develop its response to an NRR user need request. RES's response provided the technical basis for RIS 2004-03. This RIS identified circuit issues to be inspected and other lower risk issues subject to inspection and needing additional research for final determination. This additional research is necessary to determine if those items of lower risk should be included in the circuit analysis inspections. RES has developed a test program to address these additional tests and analysis. The test program Cable Response to Live Fire (CAROLFIRE) will be performed in CY 2006. Probability values relevant to circuits analyses which are developed from this testing and analysis will be incorporated into the FRA.

RES was a primary developer of the revision of the fire protection SDP, a tool maintained by NRR as a part of the Reactor Oversight Process to evaluate the significance of fire protection inspection findings. In response to the NRR user need, RES completed the revision in FY04 with participation by industry and NRR, and incorporated the revision in Inspection Manual Chapter (IMC) 0609, Appendix F, and 0308, Attachment 3. Many of the methods developed in the Fire Risk Requantification Study (draft NUREG/CR-6850) were incorporated in simplified fashion in the revision. Since the fire protection SDP relies on the use of fire models, the fire model V&V activities will also improve the reproducibility of SDP assessments.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Complete fire model verification and validation documents and issue for 60-day public comment period	December 2004	October 2005	January 2006	RES/DRASP
Publish report on fire risk requantification, NUREG/CR-6850 (contingent on EPRI)	September 2005		September 2005	RES/DRASP
Issue draft ANS fire PRA standard for public comment (schedule dependent on ANS)	September 2005	June 2006	April 2006	RES/DRASP
Complete fire PRA review guidance for NRR specialists per 10 CFR 50.48(c) (endorsing NFPA 805)	December 2005		December 2005	RES/DRASP
Conduct second RES/EPRI fire PRA workshop	June 2006		May 2006	RES/DRASP
NRC provide public comments on ANS fire PRA standard	August 2006		August 2006	RES/DRASP
Issue Final fire model verification and validation report NUREG-1824	January 2007			RES/DRASP

EF-8 Effectiveness Strategic Plan Goal

Implementation Activity: Coherence program (NRR/ADRA/DRA & RES/DRASP)

Activities associated with coherence have been incorporated into the development work for a new Part 53 which will be a risk-informed, performance-based revision to 10 CFR Part 50.

(See EF-6.)

EF-9 Effectiveness Strategic Plan Goal

Implementation Activity: Establish guidance for risk-informed regulation: Development of Human Reliability Analysis (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: High

Secondary Priority: Medium

The NRC has issued Regulatory Guide (RG) 1.200 to describe an acceptable approach for determining the technical adequacy of PRA results for risk-informed activities. Regulatory Guide 1.200 (including the PRA standards reflected and endorsed by RG 1.200) is a high-level regulatory guide, addressing what to do but not how to do it. Consequently, there may be several approaches to addressing certain analytical elements, which may meet the RG 1.200 and associated standards but may do so by making different assumptions and approximations and, therefore, may have different results. This is particularly true for HRA, which is still evolving.

The staff, supported by Sandia National Laboratories, is developing guidance for performing and reviewing HRAs. The first step was to NUREG-1792, "Good Practices for Implementing Human Reliability Analysis," April 2005. The HRA good practices are generic nature, that is, they are not tied to any specific quantification methods available to estimate human error probabilities. The second phase is to evaluate those HRA methods commonly used in regulatory applications, for their capabilities to satisfy the good practices. Knowing how a particular HRA method fares with respect to good practices provides a starting point for analysts to determine whether a given analysis is appropriate and of sufficient quality for the risk-informed decision. Therefore, these evaluations provide to NRC staff a technical basis for developing review questions and assessing the quality of analyses submitted. In addition, should be useful to analysts preparing HRAs and other submittals that require human performance considerations. The evaluations were documented in NUREG-1842, "Evaluation of Human Reliability Analysis Methods Against Good Practices" in September 2006. The work is being performed as part of NRC's "Action Plan— Stabilizing The PRA Quality Expectation and Requirements," Appendix, SECY-04-0118, Task 3.2.3.

The staff is also developing NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire." This report provides guidance regarding acceptable post-fire operator manual actions to be incorporated, by reference, in the revised Section 9.5.1, "Fire Protection Program," of the Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants (NUREG-0800).

Draft NUREG-1852 provides deterministic criteria and associated technical bases for evaluating both the feasibility and reliability of operator manual actions that licensees implement to achieve and maintain hot shutdown under fire conditions. This report was developed by RES, with the support from Sandia National Laboratories and close collaboration with NRC staff dealing fire protection programs. Draft NUREG-1852 will be submitted for public comment in October 2006 and will be revised and submitted to publication in December 2006.

Project Considerations: The HRA guidance will address many issues associated with the use of HRA in decisionmaking, including the issue of suitability of an individual method to a regulatory application, consistency among HRA practitioners in implementing HRA methods, and the absence of guidance on the rigor needed for quantification of human reliability.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Prepare draft regulatory guide on fire manual actions (DG-1136) for Commission approval	December 2004		December 2004	RES/DRASP
Publish NUREG-1792, "Good Practices for Implementing Human Reliability Analysis"	April 2005		April 2005	RES/DRASP
Revise DG-1136 on fire manual actions per public comments	July 2005	August 2005	August 2005	RES/DRASP
Submit regulatory guide on fire manual actions for publication NOTE: In SRM M060208B (January 2006) the Commission withdrew the rulemaking on post-fire manual actions	December 2005	March 2006	Canceled	RES/DRASP
Issue NUREG-1842, "Evaluation of Human Reliability Analysis Methods Against Good Practices, Draft for Public Comment"	April 2006		April 2006	RES/DRASP

Publish NUREG-1842, "Evaluation of Human Reliability Analysis Methods Against Good Practices."	September 2006		September 2006	RES/DRASP
Issue Draft NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire", Draft for Comment."	October 2006	October 2006		RES/DRASP
Submit to publication NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire."	April 2007			RES/DRASP

EF-10 Effectiveness Strategic Plan Goal

Implementation Activity: PRA review of advanced reactor applications (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed, and where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: Medium

In 2003, the staff developed a PRA plan for the development of methods, data, and tools needed for reactor-specific PRAs to support the evaluation of the design and operational characteristics of advanced reactors that are different from those of current reactors. The PRA plan considered such things as the quantification of initiating events, likely accident phenomena, accident progression, containment/confinement performance, passive systems, digital instrumentation and control systems, uncertainties, internal flooding, external events (fires and seismic events), and multiple reactor modules on a site. The work is complete on the generic PRA aspects of passive systems for advanced reactors. The staff is in the process of developing a PRA research plan, which will identify and prioritize any additional PRA research needed to support advanced reactor reviews.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
ACR-700 report on the strengths and weaknesses of the AECL PRA methodology, based on the PRA methodology used in the CANDU 6 and CANDU 9 reactor designs	March 2004		March 2004	RES/DRASP
Draft report identifying good practices for modeling passive systems for the ESBWR	September 2005		September 2005	RES/DRASP
ACR-700 report documenting all PRA work to date on the ACR-700	October 2005		September 2005	RES/DRASP
Complete draft data collections and analysis report for use in advanced reactor PRA reviews	November 2005	February 2006	February 2006	RES/DRASP
Complete a report on modeling an ESBWR passive system in a PRA, including an assessment of the impacts from using enhanced passive system PRA modeling as compared to the traditional PRA practice	February 2006	November 2006		RES/DRASP

EF-11 Effectiveness Strategic Plan Goal

Implementation Activity: Developing a framework for incorporating risk information in the NMSS regulatory process (NMSS/SFPO/TRD)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY-04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: Low

In the SRM for SECY-99-100, dated June 28, 1999, the Commission approved the staff's proposed framework for risk-informed regulation in NMSS. The NMSS Risk Task Group (RTG) implemented this framework in three phases. Phase 1 established a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information. In Phase 2, RTG applied this systematic approach to identify regulatory applications amenable to being risk-informed.

Also as part of Phase 2 NMSS, in cooperation with RES/DRAA and its contractor, Brookhaven National Laboratory, developed material and waste risk guidelines and a decision-making process for risk-informing regulatory activities in NMSS. The risk guidelines are one factor considered in this systematic decision-making process, which also addresses other factors, including defense-in-depth and value-impact analysis. An initial version of a guidance document describing this systematic process, and the risk guidelines, was completed in September 2004.

In FY 2005, NMSS initiated Phase 3, the implementation and trial use phase, where the applicability of proposed risk-informed decision-making guidance will be tested in the course of selected ongoing NMSS activities. Due to resource limitations, the Risk Task Group has been disbanded, and no funding specifically for risk-informing is budgeted. Instead risk-informing will be carried out as a part of normal budgeted activities and as part of the NMSS continuous improvement process.

The guidance document on risk-informed decision-making was modified during 2005 to reflect direction in the Staff Requirements Memorandum to SECY-04-0182, and to remove sensitive

information. This completed document was then made available for trial use by staff. In January 2006 a presentation was made to the ACNW on this document. On May 2, 2006, the ACNW provided a letter to the Commission recommending use of the guidance. A workshop on the guidance was held for NMSS staff in June 2006. A synopsis of this guidance document will be produced during 2007 to facilitate staff use and training.

Further revision of the guidance will be completed in 2007, based on experience and comments during trial applications.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Develop revised draft Risk Guidelines Report	June 2004		September 2004	NMSS/RTG
Develop revised draft systematic decision-making process guidance document	June 2004		September 2004	NMSS/RTG
Present revised risk-informed decision-making guidance to ACNW	January 2006		January 2006	NMSS/SFPO/TRD
Hold workshop for NMSS staff on risk-informed decision-making	June 2006		June 2006	NMSS/SFPO/TRD
Produce Synopsis of Risk-Informed Decision-Making guidance document	June 2007			NMSS/SFPO/TRD
Revise guidance document based on comments and experience	December 2007			NMSS/SFPO/TRD

EF-14 Effectiveness Strategic Plan Goal

Implementation Activity: Probabilistic risk assessment of dry cask storage systems (NMSS/SFPO/TRD and RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: Medium

SFPO and RES staff have been conducting a probabilistic risk assessment (PRA) of a spent fuel dry storage facility. This PRA study is intended to accomplish the following objectives: (a) provide a methodology to quantify the risks of dry cask storage of spent nuclear fuel and (b) apply the methodology to a specific cask design at a specific site. This effort is part of the overall effort to develop a framework for incorporating risk information in the NMSS regulatory process. The methodology and results of the PRA will provide insights to support future risk-informed regulatory decision-making activities.

In February 2003, RES completed a draft pilot PRA on dry cask storage with a specific design. RES completed a significant revision to this report in January 2005, which includes more realistic analysis in response to peer reviewer comments.

During the latest reporting period additional revisions were made to technical analyses and documentation to improve the communication of risk insights to the public. The RES and NMSS staff presented the results and insights from this revised PRA to the Advisory Committee on Nuclear Waste in July 2006. The PRA study determined that the dry cask storage operation, which was assessed for a specific nuclear plant site and a specific dry cask design, poses an insignificant risk to the public. The predominant risk is not during the storage of the dry cask, but during the handling phase due to possible dropping of the dry cask or the canister that confines the spent fuel assemblies.

Project Considerations: This activity required technical assistance and further development of analytical and computational methods. Completion of the analyses will help SFPO better communicate the realistic probabilities, consequences, and risks associated with dry cask storage

of spent fuel and the associated methods for analyzing risk.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession No. ML003753322) which explicitly addresses dry cask storage systems. SFPO has also developed a communication plan for public interactions involving independent spent fuel storage installations (ISFSIs) (ADAMS Accession No. ML020990496), with an emphasis on the clear identification of the risk significance of ISFSIs.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Define project scope and initiate pilot PRA (Phase I)			June 2000	RES/DRASP (NMSS/SFPO/TRD)
Conduct briefing on preliminary integrated risk results	November 2001		November 2001	RES/DRASP (NMSS/SFPO/TRD)
Complete pilot PRA and issue a preliminary report on integrated risk results	May 2002	June 2002	June 2002	RES/DRASP
Complete revised draft pilot PRA for peer review	October 2001	April 2003	February 2003	RES/DRASP
Complete another revised draft pilot PRA for peer review	August 2004	January 2005	January 2005	RES/DRASP
Conduct briefing on final pilot PRA for ACNW	June 2003	September 2006	July 2006	RES/DRASP (NMSS/SFPO/TRD)
Issue final pilot PRA as NUREG	September 2006		September 2006	RES/DRASP

EF-15 Effectiveness Strategic Plan Goal

Implementation Activity: **Interagency Jurisdictional Working Group Evaluating the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium and/or thorium (NMSS/IMNS/RGB)**

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 6: Minimize unnecessary regulatory or jurisdictional overlap.

Secondary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Strategy 6: Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory processes.

Primary Priority: N/A

Secondary Priority: N/A

The Part 40 Jurisdictional Working Group includes a representative from various Federal agencies and a representative from the States (representing the Organization of Agreement States and the Conference of Radiation Control Program Directors). The working group evaluated current jurisdictional authorities for the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium or thorium. The working group has found that most materials and processes are regulated by some regulatory agency. The working group analyzed available technical data to assist its assessment of risks to workers and the public from uranium and thorium below 0.05 percent by weight concentration, including a review of the results of NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material." The working group concluded that the results in NUREG-1717 were based on conservative assumptions and that the doses are actually much lower than those given in the NUREG. However, there may be other scenarios, related to other industries that were not evaluated, that could result in exposures to workers and members of the public. Therefore, the working group believes that some oversight of the material subject to this exemption is needed. SECY-03-0068, dated May 1, 2003, was submitted to the Commission for review.

The Commission issued a staff requirements memorandum (SRM) on October 9, 2003, for this SECY paper. The Commission partly approved and partly disapproved the recommendation of the staff. The Commission does not want the staff to continue to pursue legislation at this time, because the Commission does not believe legislation will be approved by Congress. However,

the Commission does want the staff to continue, as a low priority, to gauge the level of support with other Federal agencies and the States and explore other possible approaches to rationally treating these materials.

The staff plans to solicit (1) comments from the individual States and other affected Federal agencies and (2) answers to specific questions regarding the approach discussed in the SECY paper. Once the staff has that information, the staff can evaluate the level of support for the recommendations in the SECY paper and any possible alternatives to legislation.

Project Considerations: Given the priority, this project is currently on hold pending completion of higher priority work.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Recommendations from the Part 40 Jurisdictional Working Group to the Commission	June 2002	March 2003	May 2003	NMSS/IMNS/RGB
Solicit comments from States and other Federal agencies	September 2004	December 2004	On hold	NMSS/IMNS/RGB

EF-17 Effectiveness Strategic Plan Goal

Implementation Activity: **Revise Part 36: Requirements for Panoramic Irradiators (PRM-36-01) (NMSS/IMNS/RGB)**

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Strategy 6: Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory processes.

Primary Priority: N/A

Secondary Priority: N/A

The staff used the risk information in "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (NUREG/CR-6642) in its analysis of Petition for Rulemaking PRM-36-1, which requests modification of 10 CFR 36.65(a) and (b). These regulations describe how the operation of a panoramic irradiator must be attended by qualified operators on site. The staff, with the assistance of a contractor, conducted a specific risk assessment with the presence of an onsite operator by using the models and information found in NUREG/CR-6642. In addition, a survey was conducted on historical irradiator accidents worldwide that may have been attributed to the presence or lack of an onsite operator. Based on the results of the risk assessment and the findings of the survey, the staff prepared a draft rulemaking plan to amend the regulation using a risk-informed approach.

Project Considerations: In September 2005, the staff established a working group to evaluate information obtained by NRC (after September 11, 2001) about security assessments, security inspections, and security concerns from previous NRC licensing actions that involved panoramic irradiators. The working group presented recommendation to the Petition Review Board in February 2006. A Federal Register notice denying the petition for rulemaking was published on August 18, 2006 (71 FR 47751).

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Draft rulemaking plan to EDO	August 2001	September 2001	September 2001	NMSS/IMNS/RGB
FR notice denying the petition published	August 2006		August 2006	FR notice denying the petition published

EF-18 Effectiveness Strategic Plan Goal

Implementation Activity: **Develop an alternative risk-informed approach to special treatment requirements in Part 50 to vary the treatment applied to structures, systems, and components (SSCs) on the basis of their safety significance, using a risk-informed categorization method. (NRR/ADRA/DRA)**

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste- related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: Medium

The Commission decided in 1998 to consider promulgating new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations for power reactors. Special treatment requirements for structures, systems, and components go beyond industry-established requirements for equipment classified as “commercial grade.” Special treatment requirements provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements. In March 2000, the Commission invited comments, advice, and recommendations from interested parties on the contemplated approach for this rulemaking. Beginning in September 2000, the staff worked with industry and stakeholders to resolve issues associated with industry-developed guidance intended to implement the rule. The staff has also interacted with industry on pilot activities to test the implementing guidance at four reactor sites.

The experience from guidance development was factored into development of the proposed rule. The new requirements will be given in a new section in Part 50, Section 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Plants." The staff completed preparation of the proposed rule package and sent it to the Commission in SECY-02-0176 (September 30, 2002). The proposed rule package included a draft regulatory guide (DG-1121) providing staff comments on and clarifications of the industry-proposed implementation guidance contained in draft Revision C of NEI 00-04 ("10 CFR 50.69 SSC Categorization Guideline"). A Commission briefing was conducted on November 21, 2002. The Commission's SRM dated March 28, 2003, directed the staff to publish the proposed rule for public comment. Proposed 10 CFR 50.69 was subsequently published on May 26, 2003, for a 75-day comment period, which was later extended by 30 days.

The staff received 26 sets of comments containing hundreds of individual comments. The staff worked to address and resolve those comments and incorporated the responses to the proposed rule comments into the final rulemaking package. In November 2003, the staff received draft Revision D of NEI 00-04. Later, in April 2004, the staff received the final draft of NEI 00-04. The staff reviewed these drafts and developed RG 1.201 (formerly DG-1121) endorsing the NEI guidance with exceptions. Given the significance of some of the exceptions, the staff decided to issue RG 1.201 for trial use.

The final rulemaking package for § 50.69 was completed and went into rulemaking concurrence in April 2004. The staff had a successful meeting with the ACRS on June 2, 2004, and the ACRS subsequently provided a letter dated June 15, 2004 (ML041690039), recommending issuance of the final rule and RG 1.201 (for trial use). By letter dated June 15, 2004 (ML041680535), the CRGR decided not to review the final rulemaking package. The final rulemaking package for § 50.69 was sent to the Commission on June 30, 2004. The Commission approved the final rule, with some modifications, in an affirmation session on October 7, 2004. The final rule was published in the *Federal Register* on November 22, 2004 (69 FR 68008). Due to additional modifications to draft NEI 00-04, RG 1.201 was removed from the rulemaking package. A revision of NEI 00-04 which will support issuance of a final RG 1.201 for trial use was submitted to the NRC in February 2005. Additional revisions to NEI 00-04 were developed and a preliminary copy was provided to the staff in mid-June 2005. The final RG 1.201 for trial use was transmitted to RES for publication preparation in October 2005 and published in the *Federal Register* (71 FR 6795) in February 2006.

The NRC staff revised Regulatory Guide (RG) 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance" in response to comments received by the Nuclear Energy Institute (NEI) primarily regarding the potential for misunderstanding the staff's regulatory positions presented in the original issuance of RG 1.201 in January 2006. On April 19, 2006, the staff held a public meeting to discuss the proposed revisions to RG 1.201 that addressed the NEI comments. Those in attendance were generally favorable towards the staff's proposed revisions and the meeting primarily focused on those areas of the RG 1.201 revision in which stakeholders continued to have concerns with how the staff regulatory position could be misunderstood, primarily the staff's regulatory positions associated with Sections 8.0, 11.1, and 12.1 of NEI 00-04. As a result of these discussions, a better understanding of the intent of the industry guidance was gained by the staff, which led to some additional modifications to these specific staff regulatory positions, including the deletion of the staff regulatory position on Section 11.1. During the meeting, the staff and NEI agreed to

have additional discussions and share information in the future on the subject of proposed treatment practices under 10 CFR 50.69.

Revision 1 of RG 1.201 was completed and made available to the public (via the NRC website) on April 28, 2006. The federal register notice was issued on May 5, 2006 (71 FR 6795)

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Complete RG 1.201 for publication	June 2005	September 2005	October 2005	NRR/ADRA/DRA/APLA (D. Harrison, x3587)

EF-20 Effectiveness Strategic Plan Goal

Implementation Activity: Reactor Oversight Process (ROP) support (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 2: Develop systematic improvements in NRC's regulatory program to ensure the safe use and management of radioactive materials.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 6: Conduct NRC safety oversight programs, including inspections and enforcement activities, to monitor licensee performance.

Primary Priority: High

Secondary Priority: Medium

The NRC's ROP uses a variety of tools to monitor and evaluate the performance of commercial nuclear power plants. The process is designed to focus on those plant activities most important to safety. The NRC assesses plant performance continuously and communicates its assessment of plant performance to licensees.

RES supports the ROP by developing, piloting, and supporting the implementation of the Mitigating Systems Performance Index (MSPI) and developing Risk Assessment Standardization Project (RASP) models and guidelines.

MSPI monitors risk associated with changes in performance of selected mitigating systems, accounting for plant-specific design and performance data. MSPI enhances the safety of nuclear plants by addressing known problems with the existing Safety System Unavailability Performance Indicator and providing a measure of both system reliability and system availability. The MSPI

was implemented at all operating nuclear power plants in the 2nd quarter of 2006.

RASP will improve coordination among various NRC programs that perform risk analyses of licensee performance deficiencies; will reduce the time required to perform risk analyses; will improve NRC internal and external risk communications; will provide solutions to technical issues associated with risk assessments and operating events; and will provide NRC risk analysts with sufficient information to assess the quality of licensee risk analysis results.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Participate in MSPI implementation public workshops	September 2005		September 2005	RES/DRASP
Provide training and guidance to NRR and the regions to help focus staff reviews of licensee submittals of MSPI basis documents (ongoing).	January 2006		January 2006	RES/DRASP
Provide to NRR data and guidance to help resolve issues on requirements on PRA quality to support MSPI implementation and provide input to the agency document on these PRA requirements (ongoing).	Ongoing		April 2006	RES/DRASP
Participate in staff review teams to review licensee submittals of MSPI basis documents and provide input to the NRC's review findings and documents on the licensee submittals (ongoing).	Ongoing		April 2006	RES/DRASP
Document in a memo to NRR the results of the technical analyses used to guide and focus MSPI reviews and the database used to support the technical analyses.	April 2006		April 2006	RES/DRASP

RASP Support: Develop analysis guidelines for trial use for external events (internal fire, internal flooding, seismic, and high wind) during power operations.	June 2006		March 2006	RES/DRASP
RASP support: complete trial use and update (as needed) guidelines for the expert elicitation process to be used in plant operating event analysis.	July 2006		July 2006	RES/DRASP
RASP support: develop analysis guidelines for internal events during low-power and shutdown operations, including transition risk.	August 2006	TBD		RES/DRASP
RASP support: develop analysis guidelines for calculation of large early release frequency (LERF).	September 2006	TBD		RES/DRASP

EF-21 Effectiveness Strategic Plan Goal

Implementation Activity: SPAR Model Development Program (RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 4: Use realistically conservative safety-focused research programs to resolve safety-related issues.

Strategy 8: Make timely regulatory decisions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Strategy 5: Evaluate and utilize domestic and international operational experience and events to enhance decision-making.

Strategy 6: Conduct NRC safety oversight programs, including inspections and enforcement activities, to monitor licensee performance.

Primary Priority: High

Secondary Priority: Medium

RES is developing risk assessment models known as Standardized Plant Analysis Risk (SPAR) models. SPAR models are plant-specific probabilistic risk assessment (PRA) models that model accident sequence progression, plant systems and components, and plant operator actions. They are easy-to-use tools that permit the NRC staff to perform risk-informed regulatory activities by independently assessing the risk of events or degraded conditions at operating nuclear power plants. SPAR models for internal initiating events during full-power operation are available for all 72 plant sites in the United States. Models for internal initiating events during low-power and shutdown (LP/SD) operations, for calculating large early release frequency (LERF), and for external initiating events (fires, floods, seismic events, high winds, etc.) are currently being developed.

Enhancements to the internal events (Level 1), Revision 3 SPAR models are currently being implemented. This is being accomplished through two separate efforts. The first effort involves incorporating the resolution of modeling issues that have been identified from, the results of onsite quality assurance reviews of the Revision 3 SPAR models, the results of the comparison exercise conducted with the pilot plants in the Mitigating Systems Performance Index (MSPI) Development Program, and feedback from model users. The second effort involves performing a cut-set level review of Revision 3 SPAR models against the respective plant's probabilistic risk assessment (PRA), in a manner similar to the review performed during the comparison exercise conducted with the pilot plants in the MSPI Development Program.

Integration of the low-power and shutdown, LERF, and external initiating events models with the internal events models is scheduled to begin in January 2007 to coincide with SAPHIRE version 8 software enhancements.

The staff is currently using SPAR models to support the development of the state-of-the-art reactor consequence analysis of severe accidents at nuclear power plants. Based on insights resulting from this activity, the staff plans to update the SPAR models, as appropriate, based on current plant capabilities and safety enhancements. Initially, the plants to be evaluated will be the six lead (pilot) plants in the state-of-the-art reactor consequence analysis project. In addition, the staff will update the SPAR models, as appropriate and on a plant-by-plant basis, to include plant safety enhancements resulting from Phases 1, 2 and 3 Section B.5.b assessments as the engineering and risk information on the pertinent systems become available to the staff as part of normal NRC regulatory activities.

SPAR models are used to:(1) evaluate the risk significance of inspection findings in SDP Phase 3 analyses; (2) evaluate risk associated with operational events and degraded conditions in the ASP Program; (3) identify modeling issues that are risk-significant, and rank and prioritize these issues as part of the PRA quality efforts (e.g., as part of RG 1.200); (4) support generic safety issue resolution (e.g., GSI-189 and GSI-191) by screening (or prioritizing), performing detailed analysis to determine if licensees should be required to make changes to their plants, assessing whether NRC should modify or eliminate an existing regulatory requirement, and doing flexible and quick analyses using minimum resources to perform generic studies; (5) perform analyses in support of the staff's risk-informed review of license amendments (e.g., tech spec changes, NOEDs, fire protection requirements); and (6) independently verify the Mitigating Systems Performance Index (MSPI).

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Forwarded to the EDO the annual SECY report on the status of the ASP Program and the SPAR Model Development Program.	September 2005		September 2005	RES/DRASP
Provide NRR and regional offices with semi-annual progress report for enhanced Revision 3 SPAR model accomplishments in support of the RASP.	April 2006		April 2006	RES/DRASP
Forward to the EDO the annual SECY report on the status of the ASP Program and the SPAR Model Development Program.	September 2006		September 2006	RES/DRASP
Submit to Publications a final NUREG/CR on the SPAR model parameter estimates on component reliability, initiating event frequencies, and the basis for these estimates (assuming no significant reanalysis is needed as a result of peer review comments on draft report).	January 2007			RES/DRASP
Provide NRR and regional offices with semi-annual progress report for enhanced Revision 3 SPAR model accomplishments in support of the RASP.	April 2007			RES/DRASP
Forward to the EDO the annual SECY report on the status of the ASP Program and the SPAR Model Development Program.	September 2007			RES/DRASP

EF-22 Effectiveness Strategic Plan Goal

Implementation Activity: Change technical requirements of 10 CFR 50.46, “Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,” including evaluation of a broader change to the single-failure criterion. (NRR/ADRA/DLR, RES/DRASP)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Strategy 2: Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements.

Strategy 3: Use performance-based regulation to minimize unnecessarily prescriptive requirements.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 1: Develop, maintain, and implement licensing and regulatory programs for reactors, fuel facilities, materials users, spent fuel management, decommissioning sites, and waste related activities to protect public health, safety, and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: High

In SECY-98-300, “Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities” (December 1998), the staff proposed options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. Option 3 identified possible changes to specific technical requirements in Part 50. The Commission approved the staff’s proposal in a June 1999 staff requirements memorandum (SRM).

In SECY-01-0133, “Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria),” and SECY-02-0057 (update to SECY-01-0133), the staff recommended rulemaking to change the technical requirements for the emergency core cooling systems (ECCS).

In March 2003, the Commission issued an SRM in response to SECY-02-0057 with the following directions:

1. Complete technical work on LOCA frequency estimation.
2. Prepare a proposed rule to allow for a risk-informed alternative to the present maximum break size.
3. Prepare a proposed rule with a performance-based approach to meeting ECCS acceptance criteria.
4. Proceed with rulemaking to risk-inform ECCS functional reliability requirements in GDC 35 and thus relax the current requirement for consideration of a large-break LOCA with a coincident LOOP.
5. Pursue a broader change to the single-failure criterion and inform the Commission of the staff's findings
6. Do not proceed with further revision to Appendix K allowing voluntary use of the 1994 ANS decay heat standard.

In response to item 5, the staff developed a SECY paper and associated technical report. The SECY paper, entitled "Risk-Informed and Performance-Based Alternatives to the Single Failure Criterion," was issued in August 2005 and it presents the results of the staff's technical review regarding the broader change to the single-failure criterion. The Commission responded with an SRM in September 2005 directing the staff to seek additional stakeholder involvement by making the draft technical report on the single-failure criterion available to the public. The Commission also directed the staff to include efforts to risk-inform the single-failure criterion in ongoing efforts in FY06 and beyond related to risk-informing the reactor requirements of 10 CFR Part 50.

In response to the main provisions of the SRM (items 1, 2, 3 and 4), the staff prepared SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCAs) Break Size and Plans for Rulemaking on LOCAs With Coincident Loss of Offsite Power," in which the staff requested direction and additional guidance on policy issues that would facilitate resolution of identified technical issues. The technical issues included (1) the alternate break size selection metric, (2) appropriate limitations on what modifications would be allowed in a plant and how they could change the risk profile, (3) defense-in-depth considerations, and (4) the appropriate level of mitigative capability which should remain for breaks beyond the new design basis.

In the SRM to SECY-04-0037 the Commission indicated that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than that size should be removed from the design basis event category. The Commission indicated that the proposed rule should be broadly structured to allow operational as well as design changes and should include requirements for licensees to maintain capability to mitigate the full spectrum of LOCAs up to the double-ended guillotine break of the largest reactor coolant system pipe. The Commission stated that the mitigation capabilities for beyond-design-basis events should be controlled by NRC requirements commensurate with the safety significance of these capabilities. The Commission further stated that LOCA frequencies should be periodically reevaluated and that if increases in frequency required licensees to restore the facility to its original design basis or make other changes, the backfit rule (10 CFR 50.109) would not apply.

In July 2004 the staff completed a narrative description of the conceptual basis for the proposed rule on LOCA redefinition and draft proposed rule language, both of which were posted on the NRC public Web site in August 2004 and noticed in the *Federal Register*. A public meeting was held in August 2004 during which industry stakeholders raised a number of rulemaking issues. A memorandum was sent to the Commission on October 22, 2004, summarizing the rule concept and providing the draft proposed rule language. This information was again posted on the NRC public Web site. In March 2005, the staff forwarded the proposed rule defining the risk-informed ECCS requirements and evaluation criteria for associated plant design and operational changes to the Commission (SECY 05-0052). On July 29, 2005, the Commission approved publication of the proposed rulemaking subject to comments and specific changes provided in the SRM. It also highlighted the need for additional stakeholder feedback on implementation details and directed the staff to reduce the extent to which it planned to require prescriptive regulatory requirements for breaks beyond the transition break size.

The proposed rule was issued for public comment on November 7, 2005. In response to a stakeholder request, the comment period was extended and closed on March 8, 2006. A report on seismic considerations for the transition break size was also posted for public comment on the NRC external Web site in December 2005. A public workshop to discuss the proposal was held on February 16, 2006. A public meeting was held on June 28, 2006 to discuss alternatives to resolve public comments. On July 31, 2006, draft final rule language was posted on the NRC Rule forum website and a public meeting was held on August 17, 2006, to discuss the final rule language. The staff expects the final rule to be submitted for Commission approval by the second quarter in FY-2007.

In the same SRM on SECY-04-0037 the Commission also approved the staff recommendation to finish the review of a BWROG topical report and pilot exemption requests on LOCA-LOOP before initiating a LOCA-LOOP rulemaking plan to relax the current requirements for consideration of a large break LOCA with coincident LOOP. In April 2004 the BWROG submitted its topical report for NRC review. By letter dated December 5, 2007, the staff provided the BWROG an extensive set of RAI's mostly directed toward clarifying the topical's proposal that generic risk assessment results are sufficient for reference in plant specific exemption request. At a February 14, 2006 meeting between the NRC staff and members of the BWROG, the BWROG agreed to submit a new revision to the topical report that will require a plant specific risk analysis. The BWROG submitted the new version on August 25, 2006. This represents a several month delay from the original schedule. The staff will establish a schedule for completion of the review of the topical after the revised report has been received.

The delay in the scheduled review of the BWROG topical may lead to a delay in the proposed LOCA-LOOP rule that is currently scheduled to be provided to the Commission in December 2007. This December 2007 schedule included a one year interval after completion of the review of the topical to incorporate the lessons learned from the review of the topical into the rulemaking. The staff will reassess both the need and the schedule for a LOCA-LOOP rulemaking after it receives the revised topical.

In other matters related to SECY-04-0037, the Commission directed the staff to develop a rule for performance-based ECCS acceptance criteria applicable to cladding materials other than Zircaloy or ZIRLO™. The Chairman has recently approved funding for FY06-08 to begin this work, including verification testing of M5 and ZIRLO-clad high-burnup fuel rods. A Research

Information Letter and NUREG/CR report are expected in November 2006 presenting the technical basis for the revised performance-based criteria.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Complete expert elicitation for new LOCA frequencies	December 2004		December 2004	RES/DFERR R. Tregoning
Issue SECY 05-0052 forwarding proposed rule defining alternative risk-informed option ECCS evaluation criteria and risk-informed acceptance criteria for associated plant design and operational changes	March 2004 (SRM-02-0057)	March 2005	March 2005	NRR/ADRA/DPR/PFPB R. Dudley
Issue draft NUREG report on expert elicitation results for LOCA frequencies for comment	March 2005	June 2005	June 2005	RES/DFERR R. Tregoning
Issue SECY (05-0138) on single-failure criterion	July 2004	July 2005	July 2005	RES/DRASP J. Lane
Issue proposed rule on risk-informing 50.46 for public comment	November 2005		November 2005	NRR/ADRA/DPR/PFPB R. Dudley
Issue NUREG/CR providing preliminary basis for rulemaking on 50.46(b) (oxidation limits)	June 2006	December 2006		RES/DFERR R. Meyer
Issue final NUREG report on expert elicitation results for LOCA frequencies	December 2005	December 2006		RES/DFERR A. Csontos
Provide final rule on 50.46 to Commission for approval	October 2006	2 nd Q FY 2007		NRR/ADRA/DPR/PFPB E. McKenna
Provide a regulatory guide on 50.46 implementation	December 2006	4 th Q 2007		NRR/APDS/DSS T. Collins
Complete safety evaluation of BWR LOCA-LOOP topical report	July 2004 (SRM-02-0057)	June 2007 (proposed date)		NRR/ADRA/DRA/APLA S. Dinsmore
Complete proposed rule on LOCA-LOOP and issue for public comment	July 2004 (SRM-02-0057)	December 2007		NRR/ADRA/DPR/PFPB R. Dudley

EF-23 Effectiveness Strategic Plan Goal

Implementation Activity: Risk-Informing of Standard Review Plans for Independent Spent Fuel Storage Installations and Dry Cask Storage Systems (NMSS/SFPO/TRD)

Primary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 1: Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.

Secondary FY 04-09 Strategic Plan Goal: Ensure protection of public health and safety and the environment.

Strategy 3: Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.

Primary Priority: Medium

Secondary Priority: Medium

Spent Fuel Project Office (SFPO) has initiated a project to update and risk-inform the following guidance: NUREG-1536, Standard Review Plan for Dry Cask Storage Systems, and NUREG-1567, Standard Review Plan for Spent Fuel Dry Storage Facilities. These SRPs will be updated by incorporating Interim Staff Guidance documents addressing a variety of specific technical issues that have been issued over a number of years. Specific review items will be prioritized using ranking criteria based on the potential impact that a deficiency in that item would have on public health and safety. The draft input for this risk-informed update is being produced by technical review staff of SFPO. It is expected that production of the documents in official format will be assisted by an outside contractor. The contract was awarded in October 2006, and the first draft documents will be available for SFPO management and staff comments 6 months later, in April 2007. NRC staff comments would then be provided, and the documents revised as indicated in the milestone table below.

Project Considerations:

Once the documents are in final form, they will be issued for public comment.

Selected Major Milestones and Schedules				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Draft SRPs for comment	April 2007			NMSS/SFPO/TRD
NRC comments on draft SRPs	June 2007			NMSS/SFPO/TRD
Draft final SRPs to NRC	October 2007			NMSS/SFPO/TRD
NRC comments on draft final SRPs	December 2007			NMSS/SFPO/TRD
Final SRPs to NRC	March 2008			NMSS/SFPO/TRD

CHAPTER 3. OPENNESS

Goal: Ensure Openness in Our Regulatory Process

Strategic Outcome: Stakeholders are informed and involved in NRC processes as appropriate.

3.1 Introduction

The NRC views nuclear regulation as the public's business and, as such, it should be transacted openly and candidly in order to maintain the public's confidence. The goal to ensure openness explicitly recognizes that the public must be informed about, and have a reasonable opportunity to participate meaningfully in, the NRC's regulatory processes.

Over the next several years, the public's interest in the safety and security of nuclear facilities and transportation of nuclear waste is expected to increase because of emerging issues. In particular, these issues include the anticipated license application from the Department of Energy for a high-level radioactive waste repository at Yucca Mountain, the potential increase in the number of spent nuclear fuel shipments, the increase in the number of applications to extend the operating life of reactors, applications for a variety of fuel cycle facilities, and submittal of multiple applications for reactor facilities.

As a result of the terrorist attacks on September 11, 2001, both security and emergency planning issues have become increasingly important to both the public and government officials. The NRC must, therefore, concentrate its efforts on assuring the public that its rigorous oversight and "defense-in-depth" approach ensures that the public is adequately protected, and that emergency plans surrounding the facility are well conceived and will work.

In light of increased terrorist activity worldwide, the agency has had to reexamine its traditional practice of releasing almost all documents to the public. While most important safety information would not be useful to potential terrorists and can be shared with the public, that is not true for an increasing amount of security information. The NRC will adopt policies relating to sensitive security information consistent with those at the Department of Homeland Security and other agencies. Although the NRC will withhold a relatively small amount of information that could assist potential terrorists, the agency will continue to make as much information as possible available to the public.

The focus on security has emerged at a time of renewed interest in nuclear power. Some utilities are applying to the NRC for early site permits for new reactors, and existing plants are extending their licenses so they can operate for an additional 20 years. As the NRC processes these requests, it will need to address public concerns about vulnerability to many different types of terrorist attacks without disclosing information that could aid terrorists.

The NRC believes in the importance of transparency in its communications, as well as early and meaningful public involvement in the regulatory process. The agency is committed to keeping the public informed and believes that a responsible and effective regulatory process includes an involved public that is well informed.

3.2 Openness Strategies

The NRC will employ the following strategies to ensure openness in its regulatory process:

- (1) Provide accurate and timely information to the public about the uses of and risk associated with radioactive materials.
- (2) Enhance the awareness of the NRC's independent role in protecting public health and safety and the environment.
- (3) Provide accurate and timely information about the safety performance of the licensees regulated by the NRC.
- (4) Provide a fair and timely process to allow public involvement in NRC decision-making in matters not involving sensitive unclassified, safeguards, classified, or proprietary information.
- (5) Provide a fair and timely process to allow authorized (appropriately cleared with a need to know) stakeholders involvement in NRC decision-making in matters involving sensitive unclassified, safeguards, classified, or proprietary information.
- (6) Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory process.

3.3 Current Openness Initiatives and Activities

OP-1 Improve PRA communication to stakeholders

OP-1 Openness Strategic Plan Goal

Implementation Activity: Improve PRA communication to stakeholders (NRR/ADRA/DRA)

Primary FY 04-09 Strategic Plan Goal: Ensure openness in our regulatory process.

Strategy 1: Provide accurate and timely information to the public about the uses of and risk associated with radioactive materials.

Strategy 2: Enhance the awareness of the NRC's independent role in protecting public health and safety and the environment.

Strategy 6: Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory process.

Secondary FY 04-09 Strategic Plan Goal: Ensure that NRC actions are effective, efficient, realistic, and timely.

Strategy 7: Anticipate challenges and respond quickly to changes in the regulatory and technical environment.

Primary Priority: Medium

Secondary Priority: Medium

In May 2006, the NRC staff and representatives from the Nuclear Energy Institute (NEI) briefed the Commission on the status of risk-informed and performance-based reactor regulation. As a result of that meeting, the Commission directed the staff to seek ways to communicate the purpose and use of PRAs in NRC's reactor regulatory program more transparently to the public and stakeholders (SRM M060503B).

Staff from the Offices of Nuclear Reactor Regulation (NRR), Nuclear Regulatory Research (RES), and Public Affairs (OPA) are working together to develop a range of communication approaches that will reach the agency's diverse body of stakeholders. The agency must communicate often complex information on risk-informed regulation to industry experts as well as members of the public without technical backgrounds. Additionally, the agency cannot focus on a single method of communication (e.g., additions to the website) that would exclude stakeholders who cannot access it. Therefore, the interoffice team plans four different vehicles for communicating information on risk-informed regulation.

First, a redesign of the NRC public website is underway to make information on PRA applications easier to find and more understandable to the general public. This redesign will not only allow interested parties to access the latest information quickly, but also it will draw the attention of the casual Internet browser to the agency's risk-informed activities. Updates to the public website will benefit stakeholders in Congress, industry, and public-interest groups (all of which have the needed access) and members of the public with Internet access (nearly 75 percent in the United States, according to Nielsen/NetRatings in 2004).

Second, the fact sheets related to risk (currently "Probabilistic Risk Assessment" and "Nuclear Reactor Risk"), which have not been updated since June 2003, will be rewritten to improve clarity and updated to include the latest risk-informed initiatives. These fact sheets are commonly used by OPA as references to respond to questions from the media or other stakeholders. They are also available in a prominent location on the agency's public website (a "Fact Sheets and Brochures" link from the main page) that makes them accessible to casual browsers. Updates to risk-related fact sheets will allow OPA to respond appropriately to questions from stakeholders and provide another information resource to the same users who benefit from the public website update.

Third, the staff will develop a brochure or series of brochures that present PRA and risk-informed regulation in a simple and engaging fashion. Such a brochure would be designed for a public audience, rather than expert industry stakeholders, similar to recent brochures on radiation protection (NUREG/BR-0322) and decommissioning (NUREG/BR-0325). It would be available on the public website and could be sent to schools or community groups on request, as well as provided at public meetings. New brochures on risk-informed regulation will reach members of the public who are interested in NRC's programs (possibly because of new reactor licensing, which depends heavily on risk assessment) but do not have Internet access.

Finally, the staff will evaluate (based on the success of the first three activities) the need to plan a public meeting, to provide stakeholders with information on the status of risk-informed activities. Similar broad-scope meetings have been held recently on emergency preparedness and new reactor licensing. If such a meeting is deemed necessary and is successful, the meeting could evolve into an annual symposium with speakers from the staff, industry, academia, and other stakeholders. While it is unlikely that an average member of the public would attend, a PRA public meeting would provide interested stakeholders with a forum for two-way communication on current risk-informed activities.

The table below provides the current schedule of communication activities, all of which can be addressed in the 2007 fiscal year. If a public meeting on risk-informed activities is deemed necessary and is successful, it can be extended as a continuing activity.

Selected Major Milestones and Schedule				
Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Updated fact sheets on probabilistic risk assessment and nuclear reactor risk	December 2006			OPA NRR/DRA/APLB
Redesign of risk-related pages on the NRC public website	April 2007			RES/DRASP
Brochure(s) on risk-informed regulation	October 2007			OPA NRR/DRA/APLB
Broad-scope public meeting on risk-informed activities (as needed)	October 2007			RES/DRASP