Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
March 2005

Attachment 2

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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	*U.S. Code of Federal Regulations*
CLIIP	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
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 employees

GAO	General Accounting Office (now Government Accountability Office)
GDC	general design criterion/criteria
GEM	graphical evaluation module
GL	generic letter
GQA	graded quality assurance
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
LPSD	low-power/shut down
LRS	low-risk-significant
LT	leadership team
LTR	license termination rule
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
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
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
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 increasing public confidence, the agency is considering risk-informed regulation openly, 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; ©) 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:

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

This is the latest update of the Risk-Informed Regulation Implementation Plan (RIRIP), developed in accordance with a staff requirements memorandum (SRM), dated January 4, 2001.

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 and is based on the Commission's strategic plan for FY 04-09. There is a chapter on the safety strategic plan goal and a chapter on the effectiveness 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. These goals are safety, security, openness, effectiveness, and management.

In response to the release of the new strategic plan for FY 04-09, the staff has 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 either safety or effectiveness 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 strategies and means associated with each goal. The RIRIP specifies ongoing or planned activities to implement strategic plan strategies for risk-informed regulation and:

- 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 Commission'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 are 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
- 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, safety margins, the principle of "as low as reasonably achievable" (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?
  - 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 judgment)?
  - 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, 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 providing flexibility to the licensee as to the means of 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 provide 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 affect a change in 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), 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 setting out 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 are in the final stages of completion. 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. Risk communication training has been developed and piloted for selected NRC staff and management.

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 or effectiveness. Part 2 of the RIRIP has two chapters: Chapter 1 addresses activities which have safety as the primary FY 04-09 strategic plan goal and Chapter 2 addresses activities which have effectiveness as the primary FY 04-09 strategic plan goal.

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

To highlight activity interrelationships, all of the RIRIP activities are listed below, plus related activities identified by RES, NRR, and NMSS. For example, the first activity listed is SA-1, for which six related activities were identified.

Safety (Primary FY 2004-2009 Strategic Plan Goal)

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

- SA-2 ROP Support
- SA-3 Industry Trends Program Support
- SA-4 Reactor Performance Data Collection
- SA-5 Accident Sequence Precursor (ASP)
- SA-6 SPAR Models
- EF-11 Risk-Informing NMSS Regulatory Process

SA-2 Reactor Oversight Process (ROP) support

- SA-1 Risk-Informed Assessment Process
- SA-4 Reactor Performance Data Collection

SA-3 Industry Trends Support

- SA-1 Risk-informed Assessment Process
- SA-4 Reactor Performance Data Collection
- SA-5 ASP Analyses
- SA-6 SPAR Models
- EF-3 Maintain Analytical Tools

SA-4 Reactor performance data collection program

- SA-1 Risk-Informed Assessment Process
- SA-2 ROP Support
- SA-3 Industry Trends Support
- SA-5 ASP Analyses
- SA-6 SPAR Models
- EF-18 Special Treatment Requirements
- EF-4 PTS Rule
- EF-5 Steam Generators
- SA-13 Improved Methods of Calculating Risk

- EF-7 Fire Safety Methods
- EF-3 Maintain Analytical Tools

SA-5 Accident Sequence Precursor Program

- SA-2 Reactor Oversight Process
- SA-3 Industry Trends Support
- SA-4 Reactor Performance Data Collection
- SA-6 SPAR Models

SA-6 SPAR Model Development Program

- SA-1 Risk-informed Assessment Process
- SA-2 Reactor Oversight Process
- SA-3 Industry Trends Support
- SA-4 Reactor Performance Data Collection
- SA-5 ASP Analyses
- SA-13 Improved Methods of Calculating Risk
- EF-3 Maintain Analytical Tools

SA-7 High-Level Waste

SA-8 Change technical requirements of 10 CFR 50.46 ("Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors")

- EF-2 Risk-Informed Performance-Based PRA Standards Development
- SA-10 Standard Technical Specifications

SA-9 Digital Systems PRA

SA-10 Plan and implement risk-informed standard technical specifications (STS)

- SA-8 Change technical requirements of 10 CFR 50.46 for Emergency Core Cooling Systems
- EF-2 Risk-informed Performance-Based PRA Standards Development

SA-11 Fire Protection for Nuclear Power Plants

- EF-2 Risk-Informed Performance-based PRA Standards Development
- EF-7 Fire Safety Methods

SA-12 Incorporate Risk Information into the Decommissioning Regulatory Framework

- EF-13 Systematic Decisionmaking Process Development

SA-13 Develop improved methods for calculating risk in support of risk-informing regulatory decisionmaking.

- SA-6 SPAR Models
- EF-4 PTS Rule Revision
- EF-10 PRA Review of Advanced Reactor Applications
- EF-5 Steam Generators
- EF-2 Risk-informed Performance-Based PRA Standards Development
- EF-7 Fire Safety Methods
- EF-3 Maintain Analytical Tools
- EF-14 Dry Cask PRA

SA-14 Evaluation of loss of offsite power (LOOP) events and station blackout

SA-15 Exemptions from licensing and distribution of byproduct material; licensing and reporting requirements

SA-16 Materials Licensing Guidance Consolidation and Revision

- EF-16 Review of Byproduct Materials Program

SA-17 Implementation of Part 70 revision

Effectiveness (Primary FY 2004-2009 Strategic Plan Goal)

EF-1 Creating a Risk-Informed Environment

- Relates generally to all NRC efforts to risk-inform its regulatory activities.

EF-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees

- SA-7 Special Treatment Requirements
- SA-8 Change technical requirements of 10 CFR 50.46 for Emergency Core Cooling Systems
- SA-10 Standard Technical Specifications
- SA-13 Improved Methods of Calculating Risk
- EF-7 Fire Safety Methods
- EF-2 Risk-informed Performance-Based PRA Standards Development
- EF-3 Maintain Analytical Tools
- EF-6 Develop structure for new plant licensing
- EF-11 Risk-Informing NMSS Regulatory Process

EF-3 Develop and maintain analytical tools for staff risk applications

- SA-4 Reactor Performance Data Collection
- SA-6 SPAR Models
- EF-10 PRA Review of Advanced Reactor Applications
- EF-5 Steam Generators
- SA-13 Improved Methods of Calculating Risk
- EF-7 Fire Safety Methods
- EF-2 Risk-informed Performance-Based PRA Standards Development
- EF-14 Dry Cask PRA

EF-4 Develop the technical basis for the PTS rule.

- SA-4 Reactor Performance Data Collection
- SA-13 Improved Methods of Calculating Risk
- EF-3 Maintain Analytical Tools

EF-5 Develop methods for assessing steam generator performance during severe accidents

- SA-4 Reactor Performance Data Collection
- EF-2 Risk-Informed Performance-Based PRA Standards Development
- SA-13 Improved Methods of Calculating Risk
- EF-3 Maintain Analytical Tools

EF-6 Develop structure for new plant licensing: advanced reactor framework.

- EF-10 PRA Review of Advanced Reactor Applications
- EF-2 Risk-Informed Performance-Based PRA Standards Development

EF-7 Develop and apply methods for assessing fire safety in nuclear facilities

- SA-4 Reactor Performance Data Collection
- SA-11 Fire Protection
- EF-2 Risk-Informed Performance-Based PRA Standards Development
- SA-13 Improved Methods of Calculating Risk
- EF-2 Risk-Informed Performance-Based PRA Standards Development
- EF-3 Maintain Analytical Tools
- EF-14 Dry Cask PRA

EF-8 Develop a coherence program for the reactor safety arena

- Relates generally to all NRC efforts to risk-inform reactor regulatory activities

EF-9 Establish guidance for risk-informed regulation: development of HRA

EF-10 PRA review of advanced reactor applications

- EF-6 Develop structure for new plant licensing
- SA-13 Improved Methods of Calculating Risk
- EF-3 Maintain Analytical Tools

EF-11 Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process

- EF-12 Develop Risk Guidelines for Materials and Waste Arenas
- EF-2 Risk-Informed Performance-Based PRA Standards Development
- EF-13 Systematic Decisionmaking Process Development

EF-12 Develop Risk Guidelines for the Materials and Waste Arenas

- EF-11 Risk-Informing NMSS Regulatory Process
- EF-13 Systematic Decisionmaking Process Development

EF-13 Systematic Decisionmaking Process Development

- EF-11 Risk-Informing NMSS Regulatory Process
- EF-12 Develop risk guidelines for the materials and waste arenas
- EF-16 Multiphase Review of the Byproduct Materials Program
- SA-12 Incorporate risk information into the decommissioning regulatory framework
- SA-15 Exemptions from licensing and distribution of byproduct material: licensing and reporting requirements

EF-14 Probabilistic Risk Assessment of Dry Cask Storage Systems

- EF-7 Fire Safety Methods
- EF-3 Maintain Analytical Tools

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

- SA-16 Materials Licensing Guidance
- EF-13 Systematic Decisionmaking Process Development

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 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method

- SA-4 Reactor Performance Data Collection
- SA-8 Change technical requirements of 10 CFR 50.46
- EF-2 Risk-informed Performance-Based PRA Standards Development

Figure 1

FORMAT FOR ACTIVITY DESCRIPTIONS

Activity Number:

Based on the primary Strategic Plan Goal; also includes the activity number from the October 2004 RIRIP which was based on the FY 2000-2005 Strategic Plan.

Implementation Activity:

Short description of the activity; includes responsible organization down to branch level.

Primary FY 04-09 Strategic Plan Goal:

Primary FY 04-09 Strategic Plan goal based on FY 06 planning, budgeting, and performance management (PBPM) common prioritization process.

Strategy Number:

At least one strategy - from FY 04-09 Strategic Plan. Most important strategy should be listed first. Safety strategies are listed at the beginning of the safety chapter. Effectiveness strategies are listed at the beginning of the effectiveness chapter.

Secondary FY 04-09 Strategic Plan Goal:

Secondary FY 04-09 Strategic Plan goal - from FY 06 PBPM common prioritization lists.

Strategy Number:

At least one strategy - from FY 04-09 Strategic Plan – with most important strategy first.

Primary Priority:

From the FY 06 PBPM common prioritization process (high, medium, or low).

Secondary Priority:

From the FY 06 PBPM common prioritization process (high, medium, or low).

Description of Activity:

Detailed description of activity.

Project Considerations (if any):

Selected Major Milestones and Schedule Chart:

Selected Major Milestones, Original Target Date, Revised Date, Completion Date, and NRC Responsibility.

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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; 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 they 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 some of the 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 results from these studies provided a valuable foundation in quantitative risk techniques.

For the last several years, 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 of the early actions focused on the development of skills, tools, and infrastructure for the application of 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 could be accomplished 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) and broader changes such as the adjustment of special treatment requirements.

It should be noted that, 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 activities with respect to inspection and enforcement 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 could be determined. 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 both 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.

While the prioritization in this RIRIP update is based on the FY 2006 PBPM process, the common prioritization methodology is being changed for the FY 2007 PBPM process. Therefore, in order to eliminate any confusion as to whether high or low numbers indicate higher priority, goal priorities are now 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

The following are current initiatives and activities to risk-inform regulatory applications whose primary FY 04-09 Strategic Plan goal is safety:

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

SA-2 Reactor Oversight Process Support

SA-3 Industry Trends Support

SA-4 Reactor Performance Data Collection Program

SA-5 Accident Sequence Precursor Analysis Program

SA-6 SPAR Model Development Program

SA-7 Incorporate Risk Information into the High-Level Waste Regulatory Framework.

SA-8 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”)

SA-9 Digital Systems Probabilistic Risk Assessment: Develop methods and tools for analyzing the reliability of digital systems

SA-10 Develop risk-informed improvements to the 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 decision making

SA-14 Evaluation of loss of offsite power events and station blackout.

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

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).

SA-1 Safety Strategic Plan Goal (formerly RS-MS1-1, RS-MS1-2, and RS-MS1-3)

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

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: Medium

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). For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered.

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 security cornerstone. Performance indicators used to monitor licensee performance against these cornerstones have also been developed. Performance is assessed by categorizing the indicators and inspection findings using significance thresholds to decide on agency response. Depending on the results in the various cornerstone areas, NRC will undertake additional inspections to focus on the cause of the degraded performance.

The results and lessons learned from ROP implementation are documented in annual reports to the Commission.

Assessment Cycle 1 April 2000 - March 2001 SECY-01-0114

Assessment Cycle 2	April 2001 - December 2001	SECY-02-0062
Assessment Cycle 3	January 2002 - December 2002	SECY-03-0062
Assessment Cycle 4	January 2003 - December 2003	SECY-04-0053
Assessment Cycle 5	January 2004 - December 2004	SECY-05-xxxx

The assessment process utilizes inspection and performance indicator results. 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 importance 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 resulting evaluations are then input to an assessment process (action matrix) to define the agency response, depending on both the significance of individual findings and overall cornerstone performance.

The reactor safety SDP risk-informed Phase 2 notebooks were benchmarked and, by September 30, 2003, all 71 notebooks had been revised and issued as Revision 1. In retrospect, it became important to standardize all benchmarked notebooks to match the quality of those notebooks last benchmarked, approximately the last third completed. This standardization effort is currently underway and will be completed in 2005, at which time Revision 2 of the risk-informed notebooks will be issued. Revision 2 of the notebooks will address any major changes in the licensees' probabilistic risk analysis (PRAs) to date. It is expected that the notebooks will continue to be evaluated in response to future licensee-implemented changes to the plant.

In addition, each Revision 2 notebook will include or reference basic pre-solved tables which will be available for staff review and use after completion of the Revision 2 notebooks. These 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 were selected to test the notebook's model and logic. The spreadsheet essentially represents the solution and answer key to these target set items. In addition, the staff will incorporate LERF risk aspects in both the notebooks and the associated spreadsheets. These tables are expected to be completed by the end of fiscal year (FY) 2005.

Development of a methodology which could be used to account for the added risk contribution from external events is under consideration by a task group. Based on a pilot program the task group is evaluating two potentially viable methodologies. An assessment tool incorporating one of the methodologies for use by inspectors and 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. The status of the pre-solved tables is tracked in the Director's Quarterly Status Report (DQSR).

Project Considerations: The ROP was developed with input from a wide range of stakeholders. It was piloted at a few reactors and the new program was implemented nationwide in April 2000.

Lessons learned will be shared with NMSS in its efforts to improve the materials and waste regulatory framework. As a result of the lessons learned from the Davis-Besse plant, the ROP was revised to account for needed changes in outage activities, inservice inspections, problem identification and resolution, and plant status activities.

The staff has reviewed the effectiveness of engineering design inspections and has developed a pilot inspection program to test the effectiveness of a newly developed inspection procedure.

The NRC convened a task group to assess inspector training and qualifications in light of the Reactor Oversight Process and other risk-informed initiatives. Recommendations of the task group have been incorporated into Inspection Manual Chapter IMC 1245, "Inspector Qualification Program for the Office of Nuclear Reactor Regulation Inspection Program," dated April 4, 2002.

Performance indicator information, inspection findings, and the results of the NRC assessment process are made publicly available on the NRC Web site, enhancing communication with licensees and the public. The staff is working with the industry to make PRA results and risk information more available to the public. The staff continues to evaluate the ROP for lessons learned through a periodic self-assessment process.

A Mitigating Systems Performance Index (MSPI) was jointly developed by NRC staff and industry and was evaluated for implementation. The staff will retain the SDP for inspection findings while the implementing the MSPI. Several technical issues continue to must be resolved before implementation.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Annual status report on ROP implementation	April 2005			NRR/DIPM/IIPB
Revise inspection procedures to incorporate lessons learned from Davis-Besse Lessons Learned Task Group	March 2004	January 2005	January 2005	NRR/DIPM/IIPB
Test effectiveness of newly developed inspection procedure for engineering design inspections (SECY-04-0071)	March 2005	September 2005		NRR/DIPM/IIPB
Maintain and improve SDP inspection notebooks (Revision 2)	June 2005	October 2005		NRR/DSSA/SPSB
Develop the SDP Phase 2 Pre-Solved Tables	December 2005			NRR/DSSA/SPSB
Implement the MSPI	2006			NRR/DIPM/IIPB

SA-2 Safety Strategic Plan Goal (formerly RS-MS3-1)

Implementation Activity: Reactor Oversight Process (ROP) Support (RES/DRAA/OERAB)

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 and piloting 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 availability. During 2004, the MSPI was developed and piloted for 20 plants.

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**
Memo to NRR providing NUREG report on the MSPI pilot verification	January 2005		January 2005	RES/DRAA/OERAB
RASP support: Develop final guidelines for internal events during power operation	April 2005			RES/DRAA/OERAB
RASP support: Issue final ASP expert elicitation guideline.	June 2005			RES/DRAA/OERAB
Participate in MSPI implementation public workshops	September 2005			RES/DRAA/OERAB

SA-3 Safety Strategic Plan Goal (formerly RS-MS3-2)

Implementation Activity: Industry Trends Support (RES/DRAA/OERAB)

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 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 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.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Updated trends, graphs, and charts for system studies, component studies, common-cause-failure evaluations, and initiating event evaluations through FY 2003 provided on the RES Web page.	November 2004		November 2004	RES/DRAA/OERAB
Updated trends, graphs, and charts for system studies, component studies, common-cause-failure evaluations, and initiating event evaluations through FY 2004 provided on the RES Web page.	November 2005			RES/DRAA/OERAB

SA-4 Safety Strategic Plan Goal (formerly RS-MS3-3)

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

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 is 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 is maintained with the latest quarterly data available through 08/2004.	September 2004		September 2004	RES/DRAA/OERAB
Integrated Data Collection and Coding System is maintained with the latest quarterly data available through 08/2005.	September 2005			RES/DRAA/OERAB

SA-5 Safety Strategic Plan Goal (formerly RS-MS3-4)

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

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 trending 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 600 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**
Document providing input for OCFO on significant precursors through June 2004.	October 2004		October 2004	RES/DRAA/OERAB
Document providing input for OCFO on (1) significant radiation over exposures from nuclear reactors for FY 2004 and (2) significant releases to the environment for FY 2004.	December 2004		December 2004	RES/DRAA/OERAB
Forward to the EDO the annual SECY report on the status of the ASP Program and the SPAR model development program. (WITS 199200101)	September 2005			RES/DRAA/OERAB
Document providing input for OCFO on significant precursors through June 2005.	October 2005			RES/DRAA/OERAB

SA-6 Safety Strategic Plan Goal (formerly RS-MS3-5)

Implementation Activity: SPAR Model Development Program (RES/DRAA/OERAB)

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.

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) improve the quality of PRAs, which includes identifying modeling issues that are risk-significant and ranking and prioritizing these issues as part of the PRA quality efforts (e.g., as part of RG 1.200); (4) perform analyses in support of Generic/Safety Issue resolution (e.g., GSI-189 and GSI-191) by screening (or prioritizing) analyses, doing 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 required to perform generic studies; (5) performing 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 verifying the Mitigating Systems Performance Index (MSPI).

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Document Revision 3 SPAR Model Development Project accomplishments from 9/2003 to 8/2004.	September 2004		September 2004	RES/DRAA/OERAB
Document LERF SPAR models completed from 09/2003 through 08/2004.	September 2004		September 2004	RES/DRAA/OERAB
Document LP/SD SPAR models completed from 09/2003 to 08/2004.	September 2004		September 2004	RES/DRAA/OERAB
Low -power/shutdown (LP/SD) SPAR Models: Complete revision of models for Peach Bottom and River Bend to address comments obtained during onsite QA reviews and issue for general use.	November 2004		November 2004	RES/DRAA/OERAB

LERF SPAR Models: Issue model for lead plant in second plant class to licensee in anticipation of onsite QA review.	December 2004		December 2004	RES/DRAA/OERAB
External Events SPAR Models: Complete revision of prototype model to resolve review comments and issue as final.	February 2005		February 2005	RES/DRAA/OERAB
Enhanced Rev 3 SPAR Models: Provide NRR and regional offices with progress report for first half of FY 2005 on enhanced Rev. 3 SPAR model accomplishments (including equipment failure data update and improved LOOP module).	April 2005			RES/DRAA/OERAB
LERF SPAR Models: Issue model for lead plant in third plant class to licensee in anticipation of onsite QA review.	May 2005			RES/DRAA/OERAB

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SA-7 Safety Strategic Plan Goal (formerly WS-MS1-3)

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:

In July 2003, the NRC issued the "Yucca Mountain Review Plan — Final Report" as NUREG-1804, Revision 2. The review plan 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 findings.

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 staff is using the risk insights baseline as a common reference for conducting risk-informed issue resolution activities and developing a risk-informed Yucca Mountain inspection program. The staff will refine the current total-system performance assessment (TPA) code to better enable calculations beyond 10,000 years. The staff is integrating risk insights and will develop a License Application Project Plan to guide the process for conducting and documenting the license review. 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 other regulatory activities.

Project Considerations: NRC's HLW program activities and milestones anticipated for FY 2005 have been affected by external factors such as the delay of a license application for an HLW repository by DOE from December 2004 and uncertainties in the development of a revised EPA's radiation protection standards for Yucca Mountain (40 CFR Part 197) as a result of litigation.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Develop Pre-Closure Safety Analysis (PCSA) tool for evaluating preclosure risks	September 2004	October 2004	September 2004	NMSS/HLWRS/TRD
Issue update of the consolidated Issue Resolution Status Report for issue closure using risk insights	September 2004	October 2004	December 2004	NMSS/HLWRS/TRD
Complete risk analyses and update risk insights baseline	December 2004		December 2004	NMSS/HLWRS/TRD
Develop License Application Project Plan	December 2004		December 2004	NMSS/HLWRS/TRD
Complete risk-informed issue resolution activities (agreements) using risk insights	April 2005			NMSS/HLWRS/TRD
Develop HLW inspection procedures using risk insights (Complete 7 integrated inspection procedures)	September 2004		September 2005	NMSS/HLWRS/TRD
Develop Total-system Performance Assessment (TPA) code, Version 5.0.1	September 2005			NMSS/HLWRS/TRD

SA-8 Safety Strategic Plan Goal (Formerly RS-MS8-3 and RS-MS8-4)

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/DRIP/RPRP, RES/DRAA/PRAB)**

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

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 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). The staff recommended separate rulemakings for proposed changes to (1) ECCS functional reliability requirements, (2) ECCS acceptance criteria, and (3) ECCS evaluation model requirements.

On June 20, 2002, the staff produced a technical report that concluded that it remains technically acceptable to retain all of the existing requirements in 50.46 and Appendix K in their present form as an option such that no model changes or re-analysis would be required. With respect to the acceptance criteria, the report concluded that the peak cladding temperature limit and the maximum cladding oxidation limit in 50.46 could be replaced by a performance-based requirement that would be independent of the particular zirconium-based cladding alloy being considered. As for Appendix K, the report recommended replacing the 1971 ANS decay heat standard with the 1994 standard in a new optional Appendix K along with other related revisions. The report, however, concluded that the new ECCS evaluation models making use of a revised, optional Appendix K should account for "nonconservatisms."

On July 31, 2002, the staff produced a technical report to support the development of a possible risk-informed alternative to GDC 35 on ECCS functional reliability requirements. Based on LOCA frequency and conditional loss-of-offsite power (LOOP) probability estimates, the report recommended that the staff eliminate, on a generic basis, the ECCS design requirement to assume a LOOP coincident with large-break, and possibly medium-break, LOCAs.

On March 31, 2003, the Commission issued an SRM in response to SECY-02-0057 with the following directions:

1. Complete technical work on LOCA frequency estimation by March 31, 2004.
2. Prepare a proposed rule to allow for a risk-informed alternative to the present maximum break size by March 31, 2004.
3. Prepare a proposed rule with a performance-based approach to meeting ECCS acceptance criteria by March 31, 2006.
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 by July 31, 2004.
5. Pursue a broader change to the single-failure criterion and inform the Commission of the staff's findings by July 31, 2004.

Finally, the Commission disapproved the recommendation to revise Appendix K to allow voluntary use of the 1994 ANS decay heat standard.

In response to this SRM, 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," dated March 2004, in which the staff requested direction and additional guidance on policy issues that would facilitate resolution of identified technical issues. The technical issues include (1) the alternate break size selection matrix, (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. The staff recommended finishing the review of the topical report and pilot exemption requests on LOCA-LOOP before developing a rulemaking plan. On April 27, 2004, the BWROG submitted the topical report for NRC review. In May 2004, anticipating Commission direction on these issues, the staff established a steering committee to direct and coordinate an expedited effort to issue a proposed rule.

On July 1, 2004, the Commission issued its SRM on SECY-04-0037 stating that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than this 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 stated that LOCAS 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. The Commission also directed the staff to complete the proposed rule in 6 months.

In late July 2004 the staff completed a narrative description of the conceptual basis for the proposed rule on LOCAS redefinition and draft proposed rule language, both of which were posted on the NRC public Web site on August 2, 2004. A notice of availability of this information was published in the *Federal Register* on August 2, 2004. The notice also informed stakeholders of a public meeting that was held on August 17, 2004, to obtain cost-benefit information on the planned approach for use in the regulatory analysis for the proposed rule. During the meeting, industry stakeholders raised a number of rulemaking issues that the staff later evaluated. 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 also posted on the NRC public Web site. The staff discussed the proposed rule with the ACRS subcommittee on October 28, 2004, and with the ACRS full committee on November 4, 2004, December 2, 2004, and on March 3, 2005.

On December 3, 2004, the EDO extended the schedule for this rule to allow the staff to perform sensitivity studies related to selection of the transition break size. On March 14, 2005, the ACRS recommended that the proposed rule for risk-informing 10 CFR 50.46 be released for public comment. 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.

The Commission approved the staff recommendation to develop a rule for performance-based ECCS acceptance criteria applicable to cladding materials other than zircaloy or ZIRLO™. Due to other priorities and the ongoing research work that will support the rule, this effort was not scheduled to begin until FY06.

Project Considerations: The aggressive schedule established by the Commission requires the expenditure of significant staff resources.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Complete SECY forwarding proposed rule defining alternative, risk-informed option ECCS evaluation criteria and risk-informed acceptance criteria for associated plant design and operational changes	12 months after 1st SRM 03/31/2004	March 2005	March 2005	NRR/DRIP/RPRP
Preliminary redefined LOCAS frequencies	April 2004		April 2004	RES/DET/MEB
Complete expert elicitation for final LOCAS frequencies	December 2004		December 2004	RES/DET/MEB
Prepare Commission paper on single-failure criterion	July 2004	July 2005		RES/DRAA/PRAB
Conduct public meeting to discuss proposed rule on 50.46	August 2004		August 2004	NRR/DRIP/RPRP
Issue final NUREG report on expert elicitation results for LOCAS frequencies	December 2005			RES/DET/MEB
Completion of safety evaluation of BWR LOCA/LOOP exemption request topical report	August 2006[1]	May 2007[1]		NRR/DSSA/SPSB
Complete proposed rule on LOCA/LOOP and issue for public comment	March 2007	TBD[1]		NRR/DRIP/RPRP

[1] Completion date subject to resolution of issues arising from BWR topical report , including pilot plant submittal reviews.

SA-9 Safety Strategic Plan Goal

Implementation Activity: **Digital Systems Probabilistic Risk Assessment: Develop methods and tools for analyzing the reliability of digital systems that are consistent with a risk-informed approach to decision-making. (RES/DRAA/PRAB)**

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: High

Secondary Priority: Medium

There is a lack of acceptable approaches for including software failures in a probabilistic failure model of digital systems. RES staff, with the support from the Brookhaven National Laboratory, will develop a probabilistic method for modeling failures of digital systems that can be integrated with a Probabilistic Risk Assessment (PRA). This research is based on traditional approaches (e.g., fault tree and Markov methods). The method development includes:

(a) Reviewing approaches used in the nuclear industry and other industries for reliability modeling of digital systems

(b) Developing a suitable reliability model for digital system hardware

©) Developing a suitable reliability model for digital system software

(d) Integrating the digital system's hardware and software models

(e) Integrating the combined model into a PRA.

The method development will include performing case studies using the Oconee Nuclear Power Plant's reactor protection system based on the Siemens TXS digital platform. This work will help ensure that the methods and tools for analyzing the reliability of digital systems that are being developed are consistent with a risk-informed approach to decision-making.

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.	January 2005		January 2005	RES/DRAA/PRAB
Letter report on how each agency/industry models reliability of digital systems, including failure data, and how the models are used in making decisions.	June 2005			RES/DRAA/PRAB
Letter report that documents 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.	June 2005			RES/DRAA/PRAB

SA-10 Safety Strategic Plan Goal (formerly RS-MS8-5)

Implementation Activity: **Develop risk-informed improvements to the standard technical specifications (STS). (NRR/DIPM/IROB)**

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 bring technical specification requirements into congruence 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 he 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 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) replace the current system of fixed completion times with reliance on a configuration risk management program (CRMP); (5) optimize surveillance frequencies; (6) modify LCO 3.0.3 actions to allow a risk-informed evaluation to determine whether it is better to shut down or to continue to operate; (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		NRR/DIPM/IROB
Initiative 1 - Approve TSTF-423 for BWR plants and make available via CLIIP	March 2005	August 2005		NRR/DIPM/IROB
Initiative 1 - Write safety evaluation for B&W topical report	December 2004	December 2005		NRR/DIPM/IROB
Initiative 1 - Approve TSTF-431 for B&W plants and make available via CLIIP	June 2005	March 2006		NRR/DIPM/IROB
Initiative 4 - Industry submit revised Risk Management Guide, TSTF-424, and STP pilot amendment.	June 2004	May 2005		N/A
Initiative 5 - Industry submit methodology document, Limerick pilot amendment and TSTF-425	March 2004	May 2005		N/A
Initiative 5 - Approve methodology document, Limerick pilot amendment, and TSTF-425	October 2005			NRR/DIPM/IROB
Initiative 6 - Approve TSTF-426 and make available via CLIIP	December 2004	July 2005		NRR/DIPM/IROB
Initiative 7 - Make TSTF -372 (snubbers) available via CLIIP	December 2004	May 2005		NRR/DIPM/IROB
Initiative 7 - Approve TSTF -427 (hazard barriers) and write safety evaluation	October 2005			NRR/DIPM/IROB
Initiative 7 - Make TSTF -427 (hazard barriers) available via CLIIP	December 2005			NRR/DIPM/IROB
Initiative 8	TBD			NRR/DIPM/IROB

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SA-11 Safety Strategic Plan Goal (Formerly RS-MS8-6)

Implementation Activity: Fire protection for Nuclear Power Plants. (NRR/DSSA/SPLB)

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: Medium

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

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. The final voluntary rule adding a new 10 CFR 50.48(c) was published on June 16, 2004 (69 FR 33536), and became effective on July 16, 2004. The staff is working with the industry to develop implementing guidance (NEI 04-02) for 10 CFR 50.48 (c) that will be endorsed by the NRC in a new regulatory guide expected to be issued in July 2005.

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 has completed a series of fire tests which provided insights into electrical cable performance and subsequent failures during a thermal insult. NEI also convened an expert panel to evaluate the test results. EPRI published this work in May 2002 as "Spurious Actuation of Electrical Circuits due to Cable Fires" (EPRI Report #1006961). NEI submitted NEI 00-01, Revision 1, Draft 2 to the staff in December 2004. The staff has reviewed this document and plans to endorse the document in the regulatory guide supporting the new 10 CFR 50.48(c) rule.

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 notifies licensees that circuit inspections resume in January 2005.

Project Considerations: Improvements to PRA fire 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			NRR/DSSA/SPLB
Subactivity 2: Workshop for stakeholders	October 2004		October 2004	NRR/DSSA/SPLB
Subactivity 2: Issue revision to RIS 2004-03	December 2004		December 2004	NRR/DSSA/SPLB
Subactivity 2: Provide guidance to resume circuit inspections			January 2005	NRR/DSSA/SPLB

SA-12 Safety Strategic Plan Goal (formerly WS-MS1-2)

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

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 issues with implementing the LTR 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; (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 that future legacy sites would have difficult and costly decommissioning problems. 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 are a first step in a number of planned activities to be conducted during FY 2004-FY 2007 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 that will identify the specific activities and schedules for each of the recommendations and thus define the specific work over the next few years. In general, for the LTR

analysis recommendations, in FY 2004, the staff completed a regulatory issue summary on the LTR issues, Commission-approved recommendations, and the general implementation schedule for our licensees and other stakeholders. In FY 2005 and FY 2006, staff will develop guidance for staff licensing reviews and inspections that will give further details about the risk- informed approaches to institutional controls, exposure scenarios, and risk-ranking operating sites and activities that were described in SECY-03-0069. 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 plans to develop training on the Consolidated Decommissioning Guidance and the risk-informed approach. Staff training and licensee workshops are expected during FY 2005 and thereafter, and will be customized to address the needs of the licensees and the stage of decommissioning. During FY 2005, the staff also expects to develop and begin using a graded approach based on risk insights to improve the management of decommissioning resources.

Primary Priority: High

Secondary Priority: High

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Final inspection/enforcement guidance for risk-ranking operating facilities	September 2005			NMSS/DWMEP/DCD
Final review guidance for institutional controls and scenarios	September 2006			NMSS/DWMEP/DCD

SA-13 Safety Strategic Plan Goal (formerly RS-EER1-3)

Implementation Activity: **Develop improved methods for calculating risk in support of risk-informed regulatory decision-making (RES/DRAA/PRAB)**

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 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 decision making, the NRC has ongoing activities to improve the quality of human reliability analysis (HRA). The strength of data available for HRA is a concern of practitioners and decision makers. To address this need, RES is developing 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, SECY-04-0118.

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 ©) identify and/or develop mathematical structures enabling the use of HERA data in HRA applications.

With the support of Idaho National Laboratory (INL), a data structure has been established and peer-reviewed, human events from licensee event reports have been loaded and, using the Bayesian framework, mathematical structures have been proposed and developed. In FY05, the staff plans to publish the draft NUREG/CR report on the Human Event Repository and Analysis System (submitted in December 2004), continue populating HERA with human events, release HERA beta-versions to

perspective users, develop HERA user interface per user recommendations, and perform an internal review of the letter report on Bayesian methods. This work is closely coordinated with the component failure database (CFD), also residing at INL.

This work interfaces with international activities on HRA data development, particularly those led by the Organization for Economic Co-Operation and Development (OECD) through the Nuclear Energy Agency (NEA)/Committee on the Safety of Nuclear Installations (CSNI)/Working Group Risk (WGRisk) and the Halden Reactor Project.

Primary Priority: Medium

Secondary Priority: High

Project Considerations: The development of a data repository suitable for HRA would be a step towards addressing unresolved issues in HRA. Beyond its primary objective of providing quality data for HRA applications, HERA can also provide a means of obtaining an agreement among experts on the quantification of human error. Currently the many HRA quantification methods used result in different estimates for the same human actions. The primary reason for the differences is that different methods consider different aspects of human performance. Developing a structure that reflects human performance aspects considered by many methods will help achieve an agreement among experts on the similarities and differences of methods and how the next step, a widely accepted HRA quantification method,- can be achieved. HERA structure was developed with a strong interaction of NRC and national laboratory HRA and human factors experts.

In 2005 the HERA system will be shared with domestic and international organizations.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Letter report on HRA data repository entitled Human Event Repository and Analysis (HERA)	September 2004	December 2004	December 2004	RES/DRAA/PRAB
Draft NUREG/CR on HERA System"	September 2005			RES/DRAA/PRAB
Populate HERA with human events from licensee event reports and other sources	December 2004	ongoing effort	Continual FY05 and beyond	RES/DRAA/PRAB
Develop Bayesian approaches for estimating human failure event probabilities using HERA	December 2005			RES/DRAA/PRAB
Support the international activities (CNSI and Halden) HRA data development	December 2004	ongoing effort	Continual FY05 and beyond	RES/DRAA/PRAB

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SA-14 Safety Strategic Plan Goal (formerly RS-MS3-1)

Implementation Activity: Evaluation of Loss of Offsite Power Events and Station Blackout Risk (RES/DRAA/OERAB)

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.

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.

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: High

Evaluating potential risk from the electrical-blackout grid events in the Northeast on August 14, 2003 was originally part of support for the NRC's Reactor Oversight Process (ROP) before being made a separate activity in the FY 2004 RES operating plan. The ROP uses a variety of tools to monitor and evaluate the performance of commercial nuclear power plants. The process is designed to focus on plant activities most important to safety. The NRC assesses plant performance continuously and communicates its assessment of plant performance to licensees.

NRC has an action plan for resolving electrical grid concerns resulting from the electrical blackout in the Northeast on August 14, 2003. In response to this action plan, work was completed to update

information on LOOP frequency and duration and to reevaluate the station blackout risk with updated risk assessment models for a spectrum of plants.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Using data from recent LOOP events, update the SBO LOOP frequency and duration and submit draft for internal/external review.	October 2004		October 2004	RES/DRAA/OERAB
Reevaluate SBO risk (CDF) with updated SPAR models for spectrum of plants and submit draft report for internal/ external review.	January 2005		January 2005	RES/DRAA/OERAB

SA-15 Safety Strategic Plan Goal (formerly MS-MS1-3)

Implementation Activity: **Exemptions from Licensing 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 reevaluation of the exemptions from licensing in 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 would revise the exemptions from licensing in Part 30 and the requirements for exempt distribution in Part 32. The staff proposed that the results of the systematic reevaluation of the exemptions with respect to 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 so approved are in this rulemaking. 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 those in Part 40 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, OCIO, and the Agreement State (CO).

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Recommendations from the Systematic Assessment of Exemptions and the Rulemaking Plan to Commission	June 2002	October 2002	October 2002	NMSS/IMNS/RGB
Proposed rule to EDO	May 2005			NMSS/IMNS/RGB
Final rule to EDO	12 months after proposed rule is published			NMSS/IMNS/RGB

SA-16 Safety Strategic Plan Goal (formerly MS-MS2-1)

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: Low

Secondary Priority: Low

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 and 3, 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 lesson 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/revision in FY05 and FY06.

Vol. 1 Program-Specific Guidance About Portable Gauge Licenses
Vol. 2 Program-Specific Guidance About Radiography Licenses
Vol. 8 Exempt Distribution Licenses
Vol. 9 Medical Use Licenses
Vol. 20 Administrative Licensing Procedures

Project Considerations: If revisions are needed other than administrative, the NUREG will be published for public comments. This implementing activity is related to the Multiphase Review of the Byproduct Materials Program activity and NUREG/CR 6642.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Complete Vol. 9, Revision 1	December 2004	August 2005		NMSS/IMNS/RGB
Complete Vol. 2, Revision 1	Fall 2003	February 2006		NMSS/IMNS/RGB
Complete Vol. 8, Revision 1 (Draft)	Summer 2005			NMSS/IMNS/RGB
Complete Vol. 20, Revision 1	Spring 2005	September 2005		NMSS/IMNS/RGB
Complete Vol. 1, Revision 2	December 2005			NMSS/IMNS/RGB

SA-17 Safety Strategic Plan Goal (formerly MS-MS2-3)

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: High

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 available and reliable to perform their functions when needed.

In December 2001, 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 and July of 2004, 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. During 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 first eight to industry in the summer and fall of 2004.

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. The staff has initiated reviews of site-wide ISA summaries from the six operating uranium fuel fabrication facilities. These will continue through FY 2005-2006.

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 become a document that accurately reflects the facility processes and hazards and ensures 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. Efforts will continue in FY05 to risk inform similar guidance for inspections of gaseous diffusion plants.

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
Review ISA documentation	as received from licensees			NMSS/FCSS/TSG

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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 product of efficiency, means acting within a predictable time frame 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

EF-6 Develop structure for new plant licensing: advanced reactor framework.

EF-7 Develop and apply methods for assessing fire safety in nuclear facilities

EF-8 Develop a coherence program for the reactor safety arena

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 Arenas

EF-13 Systematic Decision-making Process Development

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

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 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method

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).

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EF-1 Effectiveness Strategic Plan Goal (formerly RS-EER1-1)

Implementation Activity: Creating a risk-informed environment (NRR/DSSA/SPSB)

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

Strategy 4: *Anticipate challenges and respond quickly to changes in the regulatory and technical environment.*

Strategy 8: *Make timely regulatory decisions.*

Secondary FY 04-09 Strategic Plan Goal: N/A

Primary Priority: Medium

Secondary Priority: N/A

In 2001, the Nuclear Regulatory Commission's (NRC) Office of Nuclear Reactor Regulation (NRR) initiated a program with the objective of creating an environment in which risk-informed methods are integrated into staff activities, and staff plans and actions are naturally based on the principles of risk-informed regulation. The program has four phases: (1) evaluate the current environment, (2) design an improved risk-informed environment, (3) implement changes to achieve the target environment, and (4) assess effectiveness of environmental changes. As this plan suggests, the basic strategy for the program is to first understand the current environment and then address the weaknesses and build on the strengths.

Phase 1 was designed to gather insights into staff perceptions of risk-informed regulatory practices, identify barriers to implementing risk-informed approaches, and target ideas that facilitate successful risk-informed processes. An evaluation report (ADAMS Accession No. ML022460161), completed in August 2002, characterized common themes agreed on by NRR staff and management and outlined systemic challenges related to risk-informed work activities and processes. The report was widely distributed in hard copy within NRR and the regions, and the RIE team made presentations to management teams in NRR, to divisions across the reactor program, and to several NRC professional conferences during the summer and fall of 2002. The evaluation report identified barriers to implementing risk-informed approaches and catalysts for achieving successful risk-informed processes.

Phase 2 of the program involved several pilot projects and other follow-up activities. The formal objectives for Phase 2 were to (1) define the components of a risk-informed environment from lessons learned from the environmental needs of several current NRR risk-informed technical activities being risk-informed within NRR and (2) provide technical assistance in one or more areas

of communications, training, or organization to support implementation of the activities throughout the reactor program. The following activities were completed:

- Project management support for Risk-Informed Tech Specifications Initiative 4B
- Research paper: Concepts Useful in Promoting a Risk-Informed Environment.
- Communication
  - regular publication of newsletter on risk-informed activities
  - brown bag seminar series on risk-informed activities
  - planned and organized NRC/industry workshop

In addition to these projects, the RIE team sought out experiences from both within the NRC and from the nuclear industry on what worked or did not work in risk-informing organizations or programs.

Phase 2 has been completed. A report documenting the findings from Phase 2 has been completed. The report clearly lays out the critical elements of a risk-informed environment and approaches for establishing those elements in the reactor program. A plan has been developed for implementing changes in the reactor program to enhance the current environment for risk-informed regulation. The plan was presented to the NRR Leadership Team in July 2004. This activity is on hold, pending higher priority work (i.e., work in NSIR)

Selected Major Milestones and Schedule				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Implement appropriate changes in NRR activities	March 2005	December 2005		NRR/DSSA.SPSB
Assess effectiveness	October 2004	December 2007		NRR/DSSA/SPSB

EF-2 Effectiveness Strategic Plan Goal (formerly RS-EER1-2)

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/DRAA/PRAB, NRR/DSSA/SPSB)**

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.*

Strategy 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.*

Primary Priority: High

Secondary Priority: Medium

The increased use of probabilistic risk assessments (PRAs) in the regulatory decision-making 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 decision-making.

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

NEI:

- PRA peer review guidance covering internal events at full power (Level 1 and simplified Level 2)
- Self-assessment guidance determining 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

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

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, 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 associated SRP chapter are intended to support all risk-informed activities. The staff's position on each PRA standard and industry guidance are 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 decision-making. The SRM directed the staff to engage our 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. 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 quality for risk-informed applications. Phase 4 calls for the industry to have full scope, full quantification, full uncertainty analyses PRAs that would 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 organization(s) meeting their schedules. (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[2]	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Final PRA standards issued by ANS on LP/SD	June 2002	December 2005		N/A (ANS)
RG 1.200 for trial use, including Appendix A (staff position on PRA standards issued by ASME on Level 1, LERF, full-power) and Appendix B (staff position on NEI peer review guidance and self-assessment	December 2003	February 2004	February 2004	RES/DRAA/PRAB
Appendix C (staff position on PRA standards issued by ANS on external hazards)	December 2003	August 2004	August 2004	RES/DRAA/PRAB
Pilot applications of RG1.200 for trial use	December 2004	March 2005	March 2005	NRR/DSSA/SPSB

Appendix D[1] (staff position on LP/SD standards issued by ANS	December 2004	December 2006		RES/DRAA/PRAB
Update to ASME PRA Standard: Addendum B	January 2005	June 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		N/A (NEI)
Update to ANS external events PRA standard, Revision 1	June 2005			N/A (ANS)
Issue RG 1.200 for use[1]	December 2005			RES/DRAA/PRAB
NUREG on treatment of uncertainties and use of alternate methods (draft for public review and comment)	October 2005			RES/DRAA/PRAB
Issue Reg Guide 1.200, Rev. 1 (Appendices A, B, and C)[1]	December 2005	June 2006		RES/DRAA/PRAB
Appendix E[1] (staff position on internal fire PRA standards issued by ANS)	December 2005	June 2007		RES/DRAA/PRAB
Issue integrated Level 1 PRA standard	June 2006			N/A ASME
Final internal fire standard issued by ANS	June 2006			N/A (ANS)
Implement PRA quality, Phase 3[1]	December 2008			NRR/DSSA RES/DRAA/PRAB

[1]Recognizing that control of these projects rests with the standards committees, milestones have been established by, and are under the control of, these organizations.

EF-3 Effectiveness Strategic Plan Goal (formerly RS-EER1-5)

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

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 Programs for Hands-on Analysis Integrated Reliability Evaluations) 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, Graphical Evaluation Module (GEM).

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EF-4 Effectiveness Strategic Plan Goal (formerly RS-MS8-7)

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

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). On December 31, 2002, the staff issued a draft report integrating 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 also presented the bases for possible changes to the PTS Rule.

A peer review of this report was recently completed. The peer review group generally supported the staff's methods and the staff's results and recommendations. The ACRS also reviewed the report and generally supported the staff's probabilistic risk analysis (PRA) and probabilistic fracture mechanics (PFM) methods, but expressed concerns with the staff's thermal-hydraulic (TH) methods. There will be an ACRS meeting in early March 2005 to discuss possible resolution of the Committee's concerns. Contingent on satisfactory results from that meeting, RES plans to present the PTS methods and results to NRR for NRR to use in a possible PTS rulemaking.

Primary Priority: High

Secondary Priority: Medium

Project Considerations: This work required close cooperation between three RES divisions. DRAA performed the PRA (sequence definition and frequency calculation), DSARE performed the thermal-hydraulic (TH) calculations (prediction of the down-comer pressure and temperature resulting from those sequences), and DET performed the fracture mechanics calculations (predictions of vessel failure likelihood resulting from the TH conditions). These three areas are all vitally important and very much interrelated. Therefore, the present uncertainty regarding acceptability of the TH methods and results calls into question acceptability of results from the other two disciplines and thus of the overall project.

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/DRAA/PRAB
Peer review of the final report on recommended changes in PTS screening criteria	June 2003	November 2004	December 2004	RES/DET/MEB
Final report on recommended changes associated with PTS screening criteria (to NRR)	September 2003	June 2005		RES/DET/MEB

EF-5 Effectiveness Strategic Plan Goal (formerly RS-MS8-9)

Implementation Activity: Develop methods for assessing steam generator performance during severe accidents. (RES/DRAA/PRAB)

Primary 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.*

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.*

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 large 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 utilizes materials and thermal-hydraulic analyses that DET and DSARE, respectively, have been doing for several years). DRAA is now incorporating these analyses and their results into a risk-informed framework to enable quantification of the frequency of containment bypass events from steam generator tube failures. The results from the tube failure analyses have been completed and are now being incorporated into the risk-informed framework; results of analyses of other materials that could fail before the SG tubes, thereby preventing tube failures and the resulting containment bypass (e.g., hot leg and surge line failures), will be incorporated into the risk-informed framework when they become available. Initially, the frequency of such failures resulting from postulated severe accidents will be determined, but this determination may be augmented later by consideration of steam generator tube ruptures resulting from non-severe accident initiators (e.g., main steam line breaks).

Primary Priority: High

Secondary Priority: High

Project Considerations: Current staff schedules call for application of the improved PRA model by May 2005 to an example plant to calculate the frequency of containment bypass events due to SG failures induced by severe accident conditions. However, a broad reevaluation of this project

is currently underway to assess the likelihood that the effort will be able to produce an acceptably low uncertainty in the quantitative result, without exceeding the resources available for this effort. Depending on the results of this reevaluation, the scope and schedule of this project may be modified.

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/DRAA/PRAB
Using results of the preceding major mile-stone, 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/DRAA/PRAB
Extend, generalize, and document SAI-SGTR risk analysis method	February 2004	May 2006		RES/DRAA/PRAB
Final reports	February 2004	May 2006		RES/DRAA/PRAB

EF-6 Effectiveness Strategic Plan Goal (formerly RS-MS8-10)

Implementation Activity: Develop Structure for New Plant Licensing (Advanced Reactor Framework) (RES/DRAA/PRAB)

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. It is to be technology-neutral to accommodate different reactor technologies, be risk-Informed to identify the more likely safety issues and gauge their significance, be performance-based to provide flexibility, and include defense-in-depth to address uncertainties

The structure has four major parts:

- Development of a technology-neutral framework/guideline for the regulatory structure.
- Subsequent derivation of the content of a set of technology neutral requirements.
- Development of guidance for applying the framework on a technology-specific basis.
- Development of technology-specific regulatory guides.

The work to date has focused on developing the technology-neutral framework (Part 1). 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 philosophy
- 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."

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Issue working draft for public review and comment and Commission information	December 2004		December 2004	RES/DRAA/PRAB
Hold public workshop to engage stakeholders and solicit input	March 2005		March 2005	RES/DRAA/PRAB
Issue paper to Commission with staff recommendations on policy and technical issues	July 2005			RES/DRAA/PRAB
Complete final draft of framework for public review and comment	December 2005			RES/DRAA/PRAB
Issue final framework	June 2005	June 2006		RES/DRAA/PRAB

EF-7 Effectiveness Strategic Plan Goal (formerly RS-EER1-4)

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

***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 draft NUREG/CR-6850 (EPRI 1008239), "EPRI/NRC-RES Fire PRA Methodology for Nuclear Power Facilities," and providing verification and validation (V&V) of a range of fire models. 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. In addition, RES is developing guidance to assist NRR specialists 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 members of the Committee to write and review the standard. 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 to 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 is in the preliminary stages of planning for additional tests and analysis. Probability values relevant to circuits analyses which are developed from this testing and analysis will be incorporated into the FRA.

Licensees have adopted manual actions instead of passive fire barriers or separation, in violation of 10 CFR Part 50, Appendix R, III.G.2. Since NRC and industry believe that, in most cases, manual actions are a reasonable alternative to passive fire barriers or separation and that most manual actions used by licensees for operation of a safe shutdown train during a fire do not involve any significant safety concerns, NRR has embarked on a rulemaking to allow acceptable manual actions and detection and suppression as an additional alternative to existing III.G.2 requirements. A draft rule was published in the *Federal Register* on March 7, 2005 (70 FR 10901). The rulemaking identifies criteria which the manual actions must meet. RES has supported a review of these criteria, provided risk insights from a review of IPEEEs relevant to manual actions, and supported the development of a time margin factor to ensure safe and reliable manual actions. A draft regulatory guide, DG-1136, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire," was submitted to the Commission in December 2004 as part of the rulemaking package for revising Section III.G.2 of 10 CFR Part 50, Appendix R.

RES was a primary author 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 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 public comment	December 2004	April 2005		RES/DRAA/PRAB
Publish report on fire risk requantification, NUREG/CR-6850, (contingent on EPRI)	July 2005			RES/DRAA/PRAB
Issue draft ANS fire PRA standard for public comment (schedule dependent on ANS)	September 2005			RES/DRAA/PRAB
Complete fire PRA review guidance for NRR specialists per 10 CFR 50.48(c) (endorsing NFPA 805)	December 2005			RES/DRAA/PRAB

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EF-8 Effectiveness Strategic Plan Goal (formerly RS-EER1-8)

Implementation Activity: Coherence Program (NRR/DSSA/SPSB & RES/DRAA/PRAB)

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 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.*

Primary Priority: Medium

Secondary Priority: Medium

Although a great deal of progress has been made towards risk-informing regulatory activities, the staff is aware that many existing regulations remain inconsistent with risk-informed practices (or are not coherent). Many NRC regulations and processes have evolved in a less than integrated manner over the years. For example, the risk-informed Significance Determination Processes used to evaluate performance deficiencies under the current Reactor Oversight Process (ROP) have identified numerous regulations for which non-compliance is not risk-significant. In addition, since risk was not assessed when most reactor design basis regulations were promulgated, use of the risk-informed ROP emphasizes safety issues not directly addressed in licensee final safety analysis reports or other docketed material. Furthermore, research and analysis over the years have revealed that some NRC regulations are overly conservative or unnecessarily burdensome without commensurate benefits to public safety. These regulations divert licensee and NRC resources away from more safety significant issues. There may also be inconsistencies between the approaches and the objectives that the staff has used to risk-inform various activities.

Consequently, the staff has been developing a framework to address the coherence of regulatory activities. This framework will provide an approach (guidelines and criteria) to ensure that the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another. A meeting was held in January 2005 to discuss the need for and benefit of the Coherence Plan. Effort on this activity has been suspended due to other higher priority work (e.g., the 10 CFR 50.46 rulemaking).

Selected Major Milestones and Schedules

Major Milestones	Original Target Date	Revised Date	Completion Date	NRC Responsibility
Update plan and issue for internal management review	December 2004		December 2004	RES/DRAA/PRAB
Issue Rev. 1 of plan for implementation	April 2005			RES/DRAA/PRAB
Issue draft framework for internal review*	January 2006			RES/DRAA/PRAB
Issue framework for use*	June 2006			RES/DRAA/PRAB

*The implementation and schedule of this milestone depend on approval of the implementation plan.

EF-9 Effectiveness Strategic Plan Goal (formerly RS-EER1-3)

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

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.*

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 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 in a document supporting Regulatory Guide 1.200. The staff developed and documented HRA good practices in draft NUREG-1792, "Good Practices for Implementing Human Reliability Analysis (HRA)." The staff will publish NUREG-1792 in FY 05 and will evaluate currently used HRA methods for their ability to meet the HRA good practices. This effort will involve interaction with domestic and international developers and users of HRA methods. This 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 regulatory guidance in support of the fire manual actions rulemaking. In FY 04 the staff developed the draft regulatory guide DG-1136, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire." In FY05 the staff will address public comments and prepare a final regulatory guide.

Primary Priority: High

Secondary Priority: Medium

Project Considerations: The HRA guidance will address many issues associated with the use of HRA in decision making, 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**
Submit NUREG-1792 on HRA good practices, for public comment	September 2004		August 2004	RES/DRAA/PRAB
Revise NUREG-1792 per public comments (final phase)	December 2004		December 2004	RES/DRAA/PRAB
Publish NUREG-1792,	April 2005			RES/DRAA/PRAB
Letter report on the evaluation of current HRA methods with respect to HRA good practices	December 2005			RES/DRAA/PRAB
Prepare draft regulatory guide on fire manual actions (DG-1136) for Commission approval	December 2004		December 2004	RES/DRAA/PRAB
Revise DG-1136 on fire manual actions per public comment	July 2005			RES/DRAA/PRAB
Submit regulatory guide on fire manual actions for publication	December 2005			RES/DRAA/PRAB

EF-10 Effectiveness Strategic Plan Goal (formerly RS-MS8-8)

Implementation Activity: **PRA Review of Advanced Reactor Applications (RES/DRAA/PRAB)**

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 of 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 staff has 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 considers 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. Work on the plan is ongoing. Specifically, work is continuing on the generic PRA aspects for advanced reactors, as well as on design-specific reviews (e.g., ESBWR). FY05 funding is supporting the investigation of passive system modeling and data collection activities for application to generic advanced reactor PRAs. The modeling approach is an enhancement of the current PRA modeling approach. The enhancement is that the PRA computer code uses information generated from a thermal-hydraulic code, (e.g., without the need for analyst interpretation). (MELCOR is a fully integrated, engineering-level computer code that models the progression of accidents in light-water reactor nuclear power plants. MELCOR models from steady state operating conditions to all accident scenarios while accounting for all engineered safety systems, including containment.)

The generic passive system modeling is being applied to an ESBWR-specific passive system. The ESBWR model will be assessed by comparison with and without the modeling in a plant PRA. General Electric has provided an enhanced version of the company's proprietary SBWR PRA model for the staff's use in assessing the ESBWR passive system modeling. Based on the lessons learned from this passive system modeling, a report will be prepared which identifies good practices for modeling passive systems, potential modeling pitfalls, and the shortcomings of

various modeling methods. Because of Dominion's withdrawal of interest in the ACR-700 and in conformance with AECL's letter, dated February 16, 2005, the work on the ACR-700 is in the process of an orderly shutdown with the preparation of documentation to summarize all of the information learned. This work started with the CANDU3 information (an AECL application subsequently withdrawn) and it is possible that the ACR-700 (or a subsequent design) may become active at some time in the future. This information will be documented so that it will be available if needed in the future.

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/DRAA/PRAB
ESBWR report identifying good practices for modeling passive systems.	July 2005			RES/DRAA/PRAB
ACR-700 report documenting all of the PRA work to date on the ACR-700	August 2005			RES/DRAA/PRAB

EF-11 Effectiveness Strategic Plan Goal (formerly MS-EER1-1)

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-04-09Strategic 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) has been implementing 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 the systematic approach developed in Phase 1 to identify NMSS regulatory applications amenable to being risk-informed. Both phases have been successfully completed.

Phase 3 involved the implementation of risk-informed initiatives and activities, including those identified in Phase 2. Phase 3 developmental activities have now been completed, including:

- development of draft risk guidelines (joint effort with RES)
- development of proposed systematic decision-making process guidance document

The next phase will be trial applications of this systematic decision-making guidance in the normal course of division regulatory activities. Since the developmental phase is complete, the Risk Task Group has been eliminated. Further coordination of this guidance will be by the SFPO Technical Review Directorate.

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/SFPO/TRD (NMSS/RTG)
Develop revised draft systematic decision-making process guidance document	June 2004		September 2004	NMSS/SFPO/TRD (NMSS/RTG)

EF-12 Effectiveness Strategic Plan Goal (formerly MS-EER1-4)

Implementation Activity: Develop Risk Guidelines for the Materials and Waste Areas (NMSS/SFPO/TRD and RES/DRAA/PRAB)

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

As outlined in a user need memo dated January 30, 2002, sent to the Office of Nuclear Regulatory Research (RES), the Risk Task Group (RTG) intended to cooperate with RES to develop material and waste risk guidelines and risk metrics, tools, methods, data, guidance, and standards necessary for implementing risk-informed approaches in NMSS. In response to the user need memo, RES initiated a contract with the Brookhaven National Laboratory to continue to support the NMSS risk-informed initiatives from the prior efforts. During FY 2003, BNL submitted a progress report on risk guideline development and briefed the PRA Steering Committee.

Furthermore, NMSS is developing a systematic decision-making process (see MS-EER1-6) for materials and waste applications. Risk guidelines are one element used in this decision-making process. Draft Revision 0 of the risk guidelines document was completed in April 2003. Revision 1 of the same document was completed in September 2003, followed by Rev. 2 of the risk guidelines document in January 2004. Rev. 3 of the guidance document was completed in September 2004, completing the developmental phase of the risk guidelines. Beginning in FY 2005, NMSS intends to start the trial use phase, where the applicability of proposed risk guidelines will be tested in various real-life NMSS applications.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Revision 0 of draft risk guidelines report	April 2003		April 2003	NMSS/SFPO/TRD (NMSS/RTG)
Revision 1 of draft risk guidelines report	September 2003		September 2003	NMSS/SFPO/TRD (NMSS/RTG)
Revision 2 of draft risk guidelines report	January 2004		January 2004	NMSS/SFPO/TRD (NMSS/RTG)
Developmental stage of the NMSS risk guidelines	September 2004		September 2004	NMSS/SFPO/TRD (NMSS/RTG)

EF-13 Effectiveness Strategic Plan Goal (formerly MS-EER1-6)

Implementation Activity: **Systematic Decision-making Process Development (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 StrategicPlan 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

The Risk Task Group (RTG), with support from the Brookhaven National Laboratory, developed an integrated guidance document on the systematic decision-making process. The objective of this guidance document is to facilitate consistent and systematic use of risk insights in making regulatory decisions. Revision 0 of the draft systematic decision-making guidance document was completed in February 2004. Because risk guidelines (see MS-EER1-4) play a vital role in the overall decision-making process, the staff decided to integrate the risk guidelines into the overall decision-making guidance document. Revision 0 of the integrated risk-informing guidance was completed in June 2004. Following the April briefings to ACNW, RTG incorporated feedback from the Committee in revising the integrated guidance document. Revision 1 of the guidance document was completed in October 2004. Revision 1contained guidelines for negligible risk and completed the developmental stage of the integrated systematic decision-making process. Beginning in FY 2005, NMSS will move into the trial phase where the systematic decision-making process will be tested in appropriate NMSS applications selected in accordance with criteria provided in the guidance document.

To ensure that the proposed decision-making algorithms are appropriate for NMSS applications, RTG has conducted several pilot studies to test the guidance document during the developmental phase of the systematic decision-making process guidance document. These are described in the following paragraphs.

<u>IMNS Pilot Study</u>

This pilot study relates to the regulatory requirements for the control and accountability of chemical agent detectors and monitors used by the U.S. Army. The large number of detectors and monitors (approximately 60,000) combined with the potential for continuing frequent loss of these devices (19 detectors have been lost within 18 months), requires significant regulatory resources, which may not be commensurate with the health significance of the loss of these devices. Using this draft guidance document and the risk information contained in NUREG/CR-6642, RTG/IMNS generically addressed the risk significance of these devices and proposed some form of regulatory burden reduction (e.g., the use of enforcement discretion). This pilot study was completed in December 2003 to support the staff's activities under SECY-03-0167, "Proposed License Amendment and Enforcement Action for the US Military."

SFPO Pilot Study

RTG and SFPO initiated a spent fuel storage pilot study on July 9, 2003. The purpose of the storage pilot study is to (1) test the effectiveness of the NMSS systematic decision-making process and draft risk guidelines and (2) identify risk insights that could enhance specific aspects of licensing reviews for spent fuel storage in dry casks. This pilot study, which was completed in December 2003, identified a number of needed revisions and additions to the systematic decision-making process.

Uranium Recovery Pilot Study

With the assistance of OSTP, FCSS, and the Agreement States, RTG applied the proposed systematic decision-making process to evaluate the effectiveness of the uranium recovery program in the third pilot study. Progress made to date indicates that the concept of risk-informing NMSS with the proposed systematic decision-making process is viable. However, additional modifications to the current systematic decision-making process are necessary to make it more suitable to evaluating programmatic effectiveness. The pilot study is expected to be completed by the end of FY 2004.

FCSS Pilot Study

With input from FCSS, the staff began a fourth pilot study on how to balance different risks (e.g., fire with criticality) in considering different safety designs in a licensing process. This study was based on a previous NRC decision approving a licensee's carbon dioxide fire suppression in a solvent extraction area due to criticality concerns. The goals of the study were to identify risk insights the staff used to balance different risks in license reviews and to uncover gaps in the proposed systematic decision-making process logic. The pilot study was completed at the end of FY 2004.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Complete pilot studies	September 2004		September 2004	NMSS/SFPO/TRD (NMSS/RTG)
Rev. 0 of integrated systematic decision-making process guidance report	June 2004		June 2004	NMSS/SFPO/TRD (NMSS/RTG)
Rev. 1 of integrated systematic decision-making process guidance report	September 2004		October 2004	NMSS/SFPO/TRD (NMSS/RTG)
Document developmental stage of the NMSS risk guidelines	September 2004		September 2004	NMSS/SFPO/TRD (NMSS/RTG)

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EF-14 Effectiveness Strategic Plan Goal (formerly WS-MS1-1)

Implementation Activity: Probabilistic Risk Assessment of Dry Cask Storage Systems (NMSS/SFPO/TRD and RES/DRAA/PRAB)

Primary FY 04-09Strategic 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: High

Secondary Priority: High

SFPO and RES staff has initiated a spent fuel dry storage cask probabilistic risk assessment (PRA). These PRA studies (Phase I & II) are intended to accomplish the following objectives: (a) provide methods to quantify the risks of dry cask storage of spent nuclear fuel, (b) provide insights for decision-making and improving 10 CFR Part 72 regulatory activities (Phase II), and ©) provide analytic tools that can be used to implement future waste risk guidelines and risk-informed regulatory activities (phase II). This effort will also be part of the overall collaborative effort to develop a framework for incorporating risk information in the NMSS regulatory process (see MS-EER1-1). Phase I: In February 2003, RES completed a draft pilot PRA on dry cask storage with a specific design. RES revised the draft report to incorporate comments from the peer review and issued a new draft in January 2005. The PRA pilot will be discussed with the joint ACRS/ACNW Committee in approximately July 2005. The final pilot PRA is scheduled to be published in 2006. Phase II: Additional studies are being identified to broaden the application of the pilot PRA and develop additional PRA tools and risk insights.

Project Considerations for Phase I: This activity requires technical assistance and development of analytical and computational methods. Completion of the analyses will help SFPO better define the details of a PRA for a specific design and site.

The members of the SFPO staff are taking PRA training presently offered through the TTC. Also, selected technical staff will be trained on the specific codes and methods employed in conducting this activity.

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 ISFSIs (ADAMS Accession# ML020990496), with an emphasis on the clear identification of the risk significance of ISFSIs.

Project Considerations for Phase II: Under development

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/DRAA/PRAB (NMSS/SFPO/TRD)
Conduct briefing on preliminary integrated risk results	November 2001		November 2001	RES/DRAA/PRAB (NMSS/SFPO/TRD)
Complete pilot PRA and issue a preliminary report on integrated risk results	May 2002	June 2002	June 2002	RES/DRAA/PRAB
Complete revised draft pilot PRA for peer review	October 2001	April 2003	February 2003	RES/DRAA/PRAB
Complete another revised draft pilot PRA for peer review	August 2004	January 2005	January 2005	RES/DRAA/PRAB
Conduct briefing on final pilot PRA for ACRS/ACNW	June 2003	July 2005		RES/DRAA/PRAB (NMSS/SFPO/TRD)
Issue final pilot PRA as NUREG	2006			RES/DRAA/PRAB
Develop plan for follow-up activities (Phase II)	February 2005	July 2005		RES/DRAA/PRAB (NMSS/SFPO/TRD)

EF-15 Effectiveness Strategic Plan Goal (formerly MS-EER1-5)

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: Low

Secondary Priority: Low

The Part 40 Jurisdictional Working Group (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 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 comments from the individual States and other impacted Federal agencies with 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.

Given the relatively low 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
Activity in this area is currently on hold				

EF-16 Effectiveness Strategic Plan Goal (formerly MS-EER2-1)

Implementation Activity: **Multiphase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations) (NMSS/IMNS/RGB)**

Primary 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.*

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: Low

Secondary Priority: Low

Description of Activity:

The staff used the risk information in NUREG/CR-6642, along with supplemental records from the underlying database, in its review of the "Mallinckrodt Lessons Learned" and the possible subsequent revision of the inspection and licensing guidance. Previously NMSS had established two task groups (Phase I and Phase II) to review the materials licensing and inspection program and provide recommendations. Phase I reviewed findings of the Mallinckrodt inspections of overexposures in Region I and Region III to develop lessons learned for licensing and inspection, regulatory changes, and NRC/State jurisdiction. Phase II reviewed the overall materials program and recommended changes to the existing licensing and inspection program to improve effectiveness and efficiency. Both task groups used the agency's previous performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

The staff developed an action plan for the Phase I and II recommendations. Items were identified for short-term action, long-term action, or information technology action. The greatest savings were identified for revision of Inspection Manual Chapter 2800, "Materials Inspection Program" (IMC 2800) and routine inspection procedures. The staff initiated a 15-month pilot program (Temporary Instruction 2800/033) to be implemented by the regional offices and also invited the Agreement States to participate. The staff completed the pilot program and concluded that effectiveness and efficiency improved through a more risk-informed and performance-based approach to routine inspections.

The pilot project is one of five projects described by SECY-02-0074 and incorporated into the National Materials Program Pilot Projects Implementation Plan. This plan will evaluate the blending of Agreement State and NRC resources to achieve common goals. The working group and steering group to revise IMC 2800 include representatives from OAS/CRCPD.

Project Considerations: The staff identified 20 recommendations from Phase I for specific changes to IMC 2800 and various inspection procedures. The Phase II review endorsed the majority of the Phase I recommendations. In addition, Phase II provided 24 recommendations for the broad, programmatic review of the materials program. To implement the Phase II recommendations and obtain savings for the materials inspection program, the staff revised IMC 2800 (Temporary Instruction 2800/033) to streamline administrative processes and completed a 15-month pilot program to evaluate the revised materials inspection program. Risk information was used to identify certain categories of licenses for which the inspection intervals were lengthened. The current practice of reducing the inspection interval for an individual licensee exhibiting a trend of poor performance was continued. The revisions to IMC 2800 are consistent with a more performance-based inspection style, including the way inspectors prepare for and document the results of routine inspections. The 11 inspection procedures (IP 87110 through IP 87120) associated with IMC 2800 were revised and redesignated as IP 87121 through IP 87127 for non-medical types of use and IP 87130 through 87134 for medical types of use. The revised inspection procedures were implemented in conjunction with the revised IMC 2800.

The pilot program was incorporated into the National Materials Program Pilot Projects Implementation Plan. A notation vote paper (SRM-04-0215) was issued on November 13, 2004. The SRM was issued on January 5, 2005. In SECY-04-0215, the staff concluded that NRC and Agreement State staff can work cooperatively to develop products under the blended option. But assurance of budgeted funding to support Agreement State involvement in NMP activities is needed and a set of implementing procedures must be developed to move the NMP closer to the Alliance option. The staff recommended that NRC and the Agreement States should continue to work under the blended option and within the constraints of available resources. The SRM approved the staff recommendation and directed the staff to evaluate the effectiveness of implementing the pilot project work products before initiating new projects. The staff should notify the Commission if staff resource expenditures become a significant portion of the overall resources needed to maintain the NMP.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Final Phase I group report	November 2000		November 2000	NMSS/IMNS/RGB
Final Phase II group report	August 2001		August 2001	NMSS/IMNS/RGB
Complete revision of inspection procedures for Part 35	Summer 2002		October 2002	NMSS/IMNS/RGB
IMC 2800, revised	July 2003	September 2003	October 2003	NMSS/IMNS/RGB
1. Temporary Instruction 2800/033	April 2003	July 2003	July 2003	NMSS/IMNS/RGB
2. Revised inspection procedures	October 2002	January 2003	January 2003	NMSS/IMNS/RGB
3. NMPPP final report	November 2004		November 2004	NMSS/IMNS/RGB

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EF-17 Effectiveness Strategic Plan Goal (formerly MS-RB1-1)

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: Low

Secondary Priority: Low

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 the "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.

Due to the 9/11 event, the rulemaking activity was put on hold pending an NRC-wide vulnerability evaluation.

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
Activity in this area is currently on hold				

EF-18 Effectiveness Strategic Plan Goal (formerly RS-MS8-1)

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

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 in1998 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 are current requirements imposed on structures, systems, and components that 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.

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Issue RG 1.201	June 2005			NRR/DSSA/SPSB

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