Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
April 2006

Enclosure 2

TABLE OF CONTENTS

RISK-INFORMED REGULATION IMPLEMENTATION PLAN

PART 1. RISK-INFORMED REGULATION

PART 2. RISK-INFORMED REGULATION IMPLEMENTATION ACTIVITIES

CHAPTER 1. SAFETY

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

CHAPTER 2. EFFECTIVENESS

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

LIST OF ABBREVIATIONS

ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee for Reactor Safeguards
ALARA	as low as reasonably achievable
AECL	Atomic Energy of Canada, Ltd.
ANPR	advance notification of proposed rulemaking
ANS	American Nuclear Society
AOT	allowable/allowed outage time
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
ATHEANA	A Technique for Human Event Analysis
ATWS	anticipated transient without SCRAM
BWR	boiling-water reactor
BWROG	Boiling Water Reactor Owners Group
CANDU	Canadian Deuterium-Natural Uranium Reactor
CCF	common-cause failure
CDF	core damage frequency
CFR	*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
ESBWR	(GE) economic simplified boiling water reactor
ET	Executive Team
FAVOR	a probabilistic fracture mechanics code
FCSS	Division of Fuel Cycle Safety and Safeguards (NMSS/FCSS)
FSAR	final safety analysis report
FTE	full-time employee/employees

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

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

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

FOREWORD

The NRC has for many years developed and adapted methods for doing probabilistic risk assessments (PRAs) and performance assessments (PAs) to better understand risks from licensed activities. The NRC has supported development of the science, the calculation tools, the experimental results, and the guidance necessary and sufficient to provide a basis for risk-informed regulation. By the mid-1990s, the NRC had a sufficient basis to support a broad range of regulatory activities. The Commission's 1995 PRA policy statement provides guidance on risk-informing regulatory activities. In this policy statement, the Commission said that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." This plan implements that policy.

In the policy statement, the Commission said it expected implementation of the policy statement to improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees. The movement toward risk-informed regulation has indeed sharpened the agency's (and, therefore, the licensees') focus on safety, reduced unnecessary regulatory burden, and fostered an effective, efficient regulatory process. A collateral benefit is the opportunity to update the technical bases of the regulations to reflect advances in knowledge and methods and decades of operating experience. In line with the NRC's goal of 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; (c) considering a broader range of countermeasures against these challenges; (d) explicitly identifying and quantifying uncertainties in analyses; and (e) testing the sensitivity of the results to key assumptions. A risk-informed regulatory approach can also be used to identify insufficient conservatism and provide a basis for additional requirements or regulatory actions.

RISK-INFORMED REGULATION IMPLEMENTATION PLAN

Background

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

> (1) The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.
>
> (2) PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.
>
> (3) PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.
>
> (4) The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory 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 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 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 is based on the Commission's strategic plan for FY 2004-2009. 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. The goals are safety, security, openness, effectiveness, and management.

In response to the release of the strategic plan for FY 04-09, the staff revised the RIRIP to make it consistent with the five goals in the FY 04-09 strategic plan. In this RIRIP update, each activity lists the primary and secondary strategic plan goals and strategies associated with the FY 04-09 plan. In particular, each activity listed has 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 the strategies and means for each goal. The RIRIP specifies ongoing or planned activities to implement strategic plan strategies for risk-informed regulation and includes:

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

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

2. Guidelines for Candidate Requirements, Practices, and Processes

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

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

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

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

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

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

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

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

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

3. Factors To Consider in Risk-Informed Regulation

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

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

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

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

- Defense-in-depth
- Safety margins
- ALARA principle
- Safety goals
- Performance-based implementation
- Voluntary alternatives versus mandatory requirements
- Selective implementation
- Regulatory oversight activities
- Regulatory analysis

Since risk information is to be used to complement the traditional deterministic approach, risk-informed activities must preserve certain key principles of the deterministic approach. Among these principles are the fundamental safety principles of defense-in-depth and safety margins, the principle of "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?
  - measures to provide prevention and mitigation protection?

  - use of good engineering practices (e.g., codes and standards)?
  - number and nature of barriers to radiation release?
  - emergency plans and procedures?
- What elements of defense-in-depth should be dependent upon risk information?
  - the balance between prevention and mitigation?
  - the number of barriers?
  - the need for redundancy, diversity, and independence of systems?
  - the events that need to be considered in the design?
- Do the defense-in-depth considerations in RG 1.174 apply?

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

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

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

Safety Margins

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

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

- How should safety margins be employed to account for uncertainties in engineering analysis?
  - best estimate analysis with conservative acceptance criteria?
  - specified confidence level?
  - role of codes and standards (i.e., do they inherently address safety margins)?

- How should safety margins be employed to account for uncertainty in risk?

  - parameter uncertainty; defense-in-depth (i.e., redundancy, diversity, independence)?
  - incompleteness in risk analysis (e.g., engineering judgement)?
  - model uncertainty (e.g., conservative acceptance criteria)?

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

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

The ALARA Principle

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

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

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

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

Safety Goals

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

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

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

Performance-Based Implementation

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

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

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

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

Voluntary Alternatives Versus Mandatory Requirements

The Commission has promulgated several regulations which permit reactor licensees to voluntarily implement risk-informed requirements or continue to operate under current requirements. The decision whether to give licensees this choice is determined by the backfit rule and safety considerations. In risk-informing the agency’s regulations, the staff may identify

areas where mandatory requirements are warranted. The staff will evaluate proposed new requirements in line with existing guidance.

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

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

Selective Implementation

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

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

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

Regulatory Oversight Activities

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

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

Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would change the use of resources by its licensees include an accompanying regulatory analysis. In regard to relaxation of requirements, "Regulatory Analysis Guidelines of the U.S.

Nuclear Regulatory Commission" (NUREG/BR-0058) states that a regulatory analysis should include a level of assessment that would demonstrate with sufficient reasonableness that the two following conditions are satisfied:

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

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

4. Communication Plans

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

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

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

5. Training Program

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

(This page intentionally left blank)

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 schedule and milestone information.

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 licensees are conforming to the applicable regulations and the conditions of their licenses to ensure safety and to provide timely and appropriate event assessment and response.

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

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

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

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 early actions focused on the development of skills, tools, and infrastructure for applying risk information.

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

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

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

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

The staff has also been using risk information for several years for event assessment. For example, the Accident Sequence Precursor Program determines conditional core damage probability for particular events or plant conditions. Finally, the staff is continuing various research programs to enhance its capabilities to conduct or review risk analyses. These research programs include activities to improve tools, enhance data, and identify areas where requirements can be adjusted in a risk-informed manner.

Prioritization of RIRIP Implementation Activities

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

The prioritization in this RIRIP update is based on the FY 2007 PBPM process. NRC (FY 2004-FY 2009 Strategic Plan goal priorities are listed as "high," "medium," or "low."

1.2 Safety Strategies

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

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

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

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

(4) Utilize regulatory programs and applied research effectively to anticipate and resolve safety issues.

(5) Evaluate and utilize domestic and international operational experience and events to enhance decisionmaking.

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

1.3 Current Safety Initiatives and Activities

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

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

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

SA-3 Industry Trends Program support

SA-4 Reactor Performance Data Collection Program

SA-5 Accident Sequence Precursor Analysis Program

SA-6 SPAR Model Development Program (renamed EF-21)

SA-7 Incorporate risk information into the high-level waste regulatory framework.

SA-8 Change technical requirements of 10 CFR 50.46 (renamed EF-22)

SA-9 Digital systems probabilistic risk assessment

SA-10 Develop risk-informed improvements to standard technical specifications (STS)

SA-11 Fire protection for nuclear power plants

SA-12 Incorporate risk information into the decommissioning regulatory framework

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

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

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

SA-16 Materials licensing guidance consolidation and revision

SA-17 Implementation of Part 70 revision

SA-18 Assessing performance of steam generator tubes and other reactor coolant system (RCS) components during severe accidents.

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

SA-1 Safety Strategic Plan Goal

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: High

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

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

The results and lessons learned from ROP implementation are documented in annual reports to the Commission. The latest report is Assessment Cycle 5, January 2004 through December 2004 (SECY-05-0070). The report on Assessment Cycle 6 will be issued in April 2006.

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

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

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

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

Project Considerations: A Mitigating Systems Performance Index (MSPI) was jointly developed by NRC staff and industry and was evaluated for implementation. The staff will retain the SDP for inspection findings while implementing the MSPI. However, the component outliers identified from standardized plant analysis risk (SPAR) and licensee PRA model comparisons are anticipated to be resolved by April 2006.

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

(This page intentionally left blank)

SA-3 Safety Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

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

RES has started to develop the Baseline Risk Index for Initiating Events (BRIIE) which is an industry-wide risk-informed performance indicator for initiating events. Development will address differences between the BRIIE calculations and the comparable Mitigating Systems Performance Index (MSPI) methodology that is being developed to support the Reactor Oversight Process (ROP).

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Update the NRC Web page and provide to NRR updated trends, graphs, and charts for system studies, component studies, common-cause failure evaluations, and initiating event evaluations through FY 2004.	November 2005		November 2005	RES/DRAA/OERAB
Provide to NRR the updated program plan for implementing the Baseline Risk Indicator of Initiating Events (BRIIE).	March 2006		March 2006	RES/DRASP

SA-4 Safety Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

Data 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 has been maintained with the latest FY2005 data available through August 2005.	September 2005		September 2005	RES/DRAA/OERAB
Memorandum to the Operating Experience Clearinghouse stating that the Integrated Data Collection and Coding System has been maintained FY 2005 data.	December 2005		December 2005	RES/DRAA/OERAB
Memorandum to the Operating Experience Clearinghouse to inform and update agency users of INPO's EPIX database system.	February 2006		February 2006	RES/DRASP
Memorandum to NRR and the regions documenting common-cause data evaluation.	August 2006			RES/DRASP

SA-5 Safety Strategic Plan Goal

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Provide to the EDO the annual SECY paper on the status of the ASP Program and the SPAR model development program.	September 2005		September 2005	RES/DRAA/OERAB
Provide OCFO input on significant precursors through June 2005.	October 2005		October 2005	RES/DRAA/OERAB
Provide ASP trends through FY 2004 to NRR to support the Industry Trends Program.	November 2005		October 2005	RES/DRAA/OERAB
Complete preliminary assessment of all FY 2005 ASP events to support Agency Action Review Meeting (AARM).	April 2006			RES/DRASP
Provide to the EDO the annual SECY paper on the status of the ASP Program and the SPAR model development program.	September 2006			RES/DRASP

SA-7 Safety Strategic Plan Goal

Implementation Activity: **Incorporate risk information into the high-level waste regulatory framework (NMSS/HLWRS/TRD)**

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

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

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

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

Primary Priority: High

Secondary Priority: High

Description of Activity:

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

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

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

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

Project Considerations: NRC's high-level waste program activities and milestones anticipated for Fiscal Year 2006 will be affected by external factors such as the delay of a license application for a high-level waste repository by the U.S. Department of Energy from December 2004 and uncertainties in the development of the U.S. Environmental Protection Agency's revised radiation protection standards for Yucca Mountain (40 CFR Part 197) as a result of public comment.

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

† The staff addressed all 293 key technical issue agreements using risk insights in April 2005 (see description for more detail).

†† Revised date will be established after resolution of the U.S. Geological Survey quality assurance issues and receipt of the U.S. Department of Energy responses to agreements previously identified as needing additional information. This date will also consider the need for risk-informed resolution of potential issues arising from proposed revision of 10 CFR Part 63 and from DOE modifications to repository design, operations, approaches, methods, and models during pre-licensing.

(This page intentionally left blank)

SA-9 Safety Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: Medium

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

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

(b) Development of a suitable reliability model for digital system hardware

(c) Development of a suitable reliability model for digital system software

(d) Integration of the hardware and software models for digital systems

(e) Integration of the combined model into a PRA

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

(a) Assessment of the current state of dynamic reliability methods

(b) Development of dynamic modeling requirements

(c) Determination of a method to identify system state and transition rates

(d) Quantification of system failure probabilities

(e) Integration of the methods into a PRA

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

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

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

(This page intentionally left blank)

SA-10 Safety Strategic Plan Goal

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

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

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

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: High

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

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

To date the industry and the staff have identified eight initiatives for risk-informed improvements to the STS: (1) define the preferred end state for technical specification actions (usually hot shutdown for PWRs); (2) increase the time allowed to delay entering required actions when a surveillance is missed; (3) modify the existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk); (4) replace the current system of fixed completion times with reliance on a configuration risk management program (CRMP) to determine risk-informed completion times; (5) optimize surveillance frequencies; (6) modify LCO 3.0.3 actions to allow a risk-informed evaluation to 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	July 2005	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Complete review of TSTF-423 for BWR plants	March 2005	March 2006	March 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Write safety evaluation for B&W topical report	December 2004	July 2006		NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 1: Complete review of TSTF-431 for B&W plants and make available via CLIIP	June 2005	December 2006		NRR/ADRO/DIRS
Initiative 4: Industry submit revised Risk Management Guide, TSTF-424, and STP pilot amendment	June 2004	April 2006		N/A
Initiative 5: Industry submit methodology document, Limerick pilot amendment and TSTF-425	March 2004	July 2005	February 2005	N/A
Initiative 5: Complete review of methodology document, Limerick pilot amendment, and TSTF-425	October 2005	July 2006		NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 6: Complete review of TSTF-426 and make available via CLIIP	December 2004	June 2006		NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Make TSTF -372 (snubbers) available via CLIIP	December 2004	May 2005	May 2005	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Complete review of TSTF -427 (hazard barriers) and write safety evaluation	October 2005	March 2006	March 2006	NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 7: Make TSTF -427 (hazard barriers) available via CLIIP	December 2005	June 2006		NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)
Initiative 8	TBD			NRR/ADRO/DIRS/ITSB (T. Tjader, x1187)

(This page intentionally left blank)

SA-11 Safety Strategic Plan Goal

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

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

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

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

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

Primary Priority: High

Secondary Priority: High

Subactivity 1: National Fire Protection Association Standard NFPA 805 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 May 2006.

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 notification to licensees that circuit inspections would resume in January 2005. Subsequently, the staff issued a second RIS for public comment in May 2005 to re-clarify compliance expectations regarding circuits. This RIS was completed and issued in December 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	May 2006**		NRR/ADRA/DRA/AFPB (C. Moulton, X2751)

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

SA-12 Safety Strategic Plan Goal

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

These assessments 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 to identify the specific activities and schedules for each of the recommendations and thus define the specific work over the next few years. These recommendations were combined into the Integrated Decommissioning Improvement Plan (IDIP) during FY 2005. In general, for the LTR analysis recommendations, in FY 2004, the staff completed a regulatory issue summary of the LTR issues, Commission-approved recommendations, and the general implementation schedule for our licensees and other stakeholders. As described in SECY-03-0069, the staff will develop guidance for staff licensing reviews that will give further details about the risk-informed approaches to institutional controls,

engineered barriers, and exposure scenarios. The draft guidance for these topics was completed in FY 2005 and will be finalized in FY 2006. In addition, risk-informed general guidance for inspections and enforcement activities was developed in FY 2005. During the guidance development, however, the staff will continue to implement these new approaches at specific sites. The site-specific lessons learned are expected to enhance the guidance development process.

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

Primary Priority: Medium

Secondary Priority: Medium

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

SA-13 Safety Strategic Plan Goal

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

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

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

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

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

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

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

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

The development of HERA has three aspects: (a) determine a structure for collecting information on human performance during abnormal conditions suitable for HRA and human factors, (b) populate HERA with information from nuclear power plants and other settings, and (c) identify and/or develop mathematical structures enabling the use of HERA data in HRA applications.

With the support of Idaho National Laboratory (INL), (1) a data structure has been established and peer-reviewed; (2) human events from licensee event reports have been loaded; (3) and—using the Bayesian framework—mathematical structures have been proposed and developed. In September 2005, the staff released the draft volume 1 of the NUREG/CR report on the HERA system for NRC's reviews and intends to publish it in mid-2006. The staff continues populating HERA with human events and developing the mathematical structures that will enable the use of HERA data in HRA applications. This work is closely coordinated with the Component Failure Database (CFD), also 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.

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/DRASP
Populate HERA with human events from licensee event reports and other sources	December 2004	ongoing effort	Continual FY05 and beyond	RES/DRASP
Support the international activities (CNSI and Halden) for HRA data development	December 2004	ongoing effort	Continual FY05 and beyond	RES/DRASP
Draft NUREG/CR on HERA system	September 2005		September 2005	RES/DRASP
Develop Bayesian approaches for estimating human failure event probabilities using HERA	December 2005	June 2006		RES/DRASP
Publish NUREG/CR Vol. 1 on HERA Framework	May 2006			RES/DRASP

(This page intentionally left blank)

SA-14 Safety Strategic Plan Goal

Implementation Activity: **Evaluation of loss-of-offsite-power events and station blackout risk (RES/DRASP)**

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

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

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: N/A

Secondary Priority: N/A

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**
Submit for publication—in three volumes—NUREG/CR-6890 (Reevaluation of Station Blackout Risk at Nuclear Power Plants)	November 2005		November 2005 Published: December 2005	RES/DRASP

SA-15 Safety Strategic Plan Goal

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: Medium

The staff conducted a systematic 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, some general licenses in Part 31, and the requirements for exempt distribution in Part 32. The staff proposed that the results of the systematic reevaluation of the exemptions for the regulation of source material would be addressed in a separate rulemaking addressed in SECY-01-0072, "Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22, 'General License,'" April 25, 2001. The staff is currently compiling supplemental information to SECY-01-0072, as directed by the Commission. The SRM on SECY-02-0196 was issued on November 17, 2003. The Commission directed the staff to proceed with rulemaking, but disapproved the inclusion of certain issues in the rulemaking. About half the issues approved by the Commission are in this rulemaking. The proposed rule was published on January 4, 2006 (71 FR 275). The others will be in another rulemaking.

Project Considerations: The Exemptions Working Group evaluated the requirements related to exemptions and certain generally licensed devices, identified a number of issues for consideration in

rulemaking, and developed recommendations for improving the regulatory framework for both the Part 30 exemptions from licensing for byproduct material and the Part 40 exemptions for source material. Recommendations for Part 40 were coordinated with the Part 40 Rulemaking Working Group.

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

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

SA-16 Safety Strategic Plan Goal

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

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

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

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

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

Primary Priority: High

Secondary Priority: High

Description of Activity:

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

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

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

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

Vol. 20 Administrative Licensing Procedures

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

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

SA-17 Safety Strategic Plan Goal

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: Medium

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

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

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

developed draft ISGs to further guide and document its approach to these issues. Interim staff guidance is being prepared for nine areas. NRC provided the nine ISGs to industry since the summer of 2004. Five of these have been issued in final form (ISGs 1, 3, 4, 8, and 9); two (ISGs 6 and 7) – dealing with meeting the October 1, 2004 deadline -- have been cancelled due a lack of need; and two (ISGs 2 and 7) are under revision. The staff held a workshop an additional workshop in August 2005, to discuss issues related to inspection of the ISA implementation.

The staff 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 reviews will continue through FYs 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 accurately reflect the facility processes and hazards and ensure those hazards are appropriately managed and controlled.

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

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

SA-18 Safety Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: High

Project Considerations: DRAA staff has applied the prototype method to a sample plant to calculate the frequency of containment bypass events due to SG failures induced by severe accident conditions at that plant. The staff is evaluating the prototype model and the results of its application to the sample plant to determine the nature and extent of expansions and improvements needed in the model. One area identified as needing improvement is in the area of human reliability. Also, thermal-hydraulic

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Develop logic framework for improved PRA model of scenarios identified as risk-significant, including the effects of operator actions	April 2004		April 2004	RES/DRASP
Using results of the preceding major milestone, identify scenarios, calculate the frequency of containment bypass events at an example plant, make indicated model improvements, and document the improved methods and results	August 2004		May 2005	RES/DRASP
Extend, generalize, and document the SAI-SGTR risk analysis method	February 2004	December 2006		RES/DRASP
Final reports	February 2004	March 2007		RES/DRASP

CHAPTER 2. EFFECTIVENESS

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

Strategic Outcome:

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

2.1 Introduction

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

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

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

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

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

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

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

2.2 Effectiveness Strategies

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

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

(2) Improve NRC regulation by adding needed requirements and eliminating unnecessary requirements

(3) Use performance-based regulation to minimize unnecessarily prescriptive requirements.

(4) Use realistically conservative, safety-focused research programs to resolve safety-related issues.

(5) Enhance cooperation with Federal, State, and Tribal governments and international counterparts.

(6) Minimize unnecessary regulatory or jurisdictional overlap.

(7) Anticipate challenges and respond quickly to changes in the regulatory and technical environment.

(8) Make timely regulatory decisions.

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

2.3 Current Effectiveness Initiatives and Activities

EF-1 Creating a risk-informed environment

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

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

EF-4 Develop the technical basis for the PTS rule

EF-5 Develop methods for assessing steam generator performance during severe accidents (renamed SA-18)

EF-6 Develop structure for new plant licensing

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

EF-8 Develop a coherence program for reactor safety (incorporated into EF-6)

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

EF-10 PRA review of advanced reactor applications

EF-11 Develop a framework for incorporating risk Information in the NMSS regulatory process

EF-12 Develop risk guidelines for the materials and waste areas (completed)

EF-13 Systematic decisionmaking process development (completed)

EF-14 Probabilistic risk assessment of dry cask storage systems

EF-15 Interagency Jurisdictional Working Group evaluating the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium and/or thorium

EF-16 Multiphase review of the Byproduct Materials Program

EF-17 Revise Part 36: Requirements for Panoramic Irradiators (PRM-36-01)

EF-18 Develop an alternative risk-informed approach to special treatment requirements in Part 50 to vary the treatment applied to structures, systems, and components (SSCs) on the basis of their safety significance using a risk-informed categorization method

EF-19 Develop a plan for making a risk-informed, performance-based revision to 10 CFR Part 50

.

EF-20 Reactor Oversight Process (ROP) support (formerly SA-2)

EF-21 SPAR Model Development Program (formerly SA-6)

EF-22 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”) (formerly SA-8)

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).

(This page intentionally left blank)

EF-1 Effectiveness Strategic Plan Goal

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

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

Strategy 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's) 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 the 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 in 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 followup 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 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 both from 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 issued. 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 specific activity is on hold, pending the completion of higher priority work (i.e., work in NSIR) and fulfillment of rotational assignments. However, we continue efforts outside, and in support of, this program to risk-inform our regulatory activities. For example, the Phased Approach to PRA quality is risk-informing internal and external standards. We have also developed a process to prioritize review of licensee submittals that is partially based on risk reduction benefits. There are additional activities to risk-inform regulatory activities and fill gaps. Finally, we envision re-publication of our newsletter in the near future. Full commitment to activities included in phase 3 will occur as priorities and resources permit. Also, we have a number of ongoing initiatives that are expected to increase the use of risk information in day-to-day activities.

Selected Major Milestones and Schedule				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Implement appropriate changes in NRR activities	March 2005	TBD		NRR/DRA/APOB
Assess effectiveness	October 2004	TBD		NRR/DRA/APOB

EF-2 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

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

Strategy 4: Provide a fair and timely process to allow public involvement in NRC decisionmaking 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 decisionmaking process of the NRC requires consistency in the quality, scope, methodology, and data used in such analyses. These requirements apply to PRAs developed by industry to support specific risk-informed licensing actions as well as PRAs developed by NRC staff to analyze specific technical issues or to support Commission decisions. To this end and to streamline staff review of license applications, professional societies, the industry, and the staff undertook initiatives to establish consensus standards and guidance on the use of PRA in regulatory decisionmaking.

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

ASME:

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

NEI:

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

ANS:

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

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

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

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

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

for 10 CFR 50.46 and 10 CFR 50.69 that may be less stringent than required by the March 31, 2003, SRMs.

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

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

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

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

Update to ANS external events PRA standard, Revision 1	June 2005	September 2006		N/A (ANS)
Update DG-1138, Appendix C to RG 1.200 (staff position on ANS PRA standard on external events)[1]	December 2005	September 2007		RES/DRASP
Final PRA standards issued by ANS on LP/SD	June 2002	June 2006		N/A (ANS)
Appendix D[1] (staff position on LP/SD standards issued by ANS) - for comment	December 2004	December 2007		RES/DRASP
Final internal fire standard issued by ANS	June 2006			N/A (ANS)
Appendix E[1] (staff position on internal fire PRA standards issued by ANS)	December 2005	June 2007		RES/DRASP
Issue RG 1.200, Rev. #2[1] (Appendices A, B, C, D, and E)	June 2008			RES/DRASP
Implement PRA quality, Phase 3[1]	December 2008			NRR/DRA/APLA (G. Parry, x1464) RES/DRASP
NUREG on treatment of uncertainties and use of alternate methods (draft for public review and comment)	October 2005	June 2006		RES/DRASP

[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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

(This page intentionally left blank)

EF-4 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

Project Considerations: None.

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

EF-6 Effectiveness Strategic Plan Goal

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

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

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

- safety, security, and preparedness expectations
- risk expectations
- design, construction, and operational expectations
- treatment of uncertainties
- performance-based concepts
- PRA technical acceptability

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

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

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

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Hold public workshop to engage stakeholders and solicit input	March 2005		March 2005	RES/DRASP
Issue paper to Commission with staff recommendations on policy and technical issues	July 2005		July 2005	RES/DRASP
Publish ANPR on risk-informed performance-based revision to 10 CFR Part 50[2]	April 2006			
Place current working draft of framework on RuleForum Web site to supplement the ANPR[1]	April 2006			RES/NRR/NSIR
Complete final draft of framework for public review and comment[3]	December 2005	December 2006		RES/DRASP
Paper to Commission on policy issues on level of safety and integrated risk, path forward on containment functional performance requirements and definition of defense-in-depth, and stakeholders' views on the ANPR[2]	October 2006			NRR/RES/NSIR
Issue final framework[2]	June 2005	June 2007		RES/DRASP

[2]This date is dependent on Commission approval to publish the ANPR.

[3]This date is dependent on Commission SRM in response to SECY-06-0007.

(This page intentionally left blank)

EF-7 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

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

The ACRS provided RES a very favorable letter on NUREG/CR-6850. Also, RES and EPRI held a highly successful 3-day public workshop in June 2005 on this methodology. Due to stakeholder interest, RES and EPRI are planning a second fire PRA workshop at NRC headquarters by June 2006. Industry needs this fire PRA methodology and the fire model V&V tools to justify changes to fire protection programs and NRC needs them to assess those analyses. The fire model V&V project is also a joint research program being conducted with EPRI. The draft NUREG-1824 was released

for public comment in January 2006. In addition, RES has just completed guidance based upon NUREG/CR-6850 to assist agency fire protection and risk engineers in reviewing these risk-informed analyses.

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

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

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

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

(This page intentionally left blank)

EF-8 Effectiveness Strategic Plan Goal

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

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

(See EF-6.)

(This page intentionally left blank)

EF-9 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

The staff, supported by Sandia National Laboratories, is developing guidance for performing and reviewing HRAs 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 published NUREG-1792 in April 2005 and in June 2005 completed an evaluation of currently used HRA methods for their ability to meet the HRA good practices. This effort involved interaction with domestic and international developers and users of HRA methods. The results of the evaluation will be released for public review and comment, and will be published in FY06. 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 05 the staff developed draft regulatory guide DG-1136, “Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire.” In late 2005, the staff developed a Commission policy paper recommending the withdrawal of the proposed rule and is awaiting the Commission’s decision on this recommendation.

Primary Priority: High

Secondary Priority: Medium

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Submit NUREG-1792 on HRA good practices for public comment	September 2004		August 2004	RES/DRASP
Revise NUREG-1792 per public comments (final phase)	December 2004		December 2004	RES/DRASP
Publish NUREG-1792	April 2005		April 2005	RES/DRASP
Publish NUREG/CR on the evaluation of current HRA methods with respect to HRA good practices	December 2005	September 2006		RES/DRASP
Prepare draft regulatory guide on fire manual actions (DG-1136) for Commission approval	December 2004		December 2004	RES/DRASP
Revise DG-1136 on fire manual actions per public comments	July 2005	August 2005	August 2005	RES/DRASP
Submit regulatory guide on fire manual actions for publication In SRM M060208B (January 2006) the Commission withdrew the rulemaking on post-fire manual actions	December 2005	March 2006	N/A	RES/DRASP

EF-10 Effectiveness Strategic Plan Goal

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: Medium

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). FY06 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 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 is being assessed by comparison with and without the modeling in a plant PRA. Based on the lessons learned from the ESBWR-specific passive system modeling assessment, a report will be prepared and transmitted to NRR providing the results, and potential future passive system modeling efforts will be determined. 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 has been stopped. The information learned from this work has been documented and will be published as a NUREG/CR report 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/DRASP
Draft report identifying good practices for modeling passive systems for the ESBWR	September 2005		September 2005	RES/DRASP
ACR-700 report documenting all PRA work to date on the ACR-700	October 2005		September 2005	RES/DRASP
Complete draft data collections and analysis report for use in advanced reactor PRA reviews	November 2005	February 2006	February 2006	RES/DRASP
Complete a report on modeling an ESBWR passive system in a PRA, including an assessment of the impacts from using enhanced passive system PRA modeling as compared to the traditional PRA practice	February 2006	April 2006		RES/DRASP

EF-11 Effectiveness Strategic Plan Goal

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

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

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

Secondary FY-04-09Strategic 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) had 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 this systematic approach to identify regulatory applications amenable to being risk-informed.

Also as part of Phase 2 NMSS, in cooperation with RES/DRAA and its contractor, Brookhaven National Laboratory, developed material and waste risk guidelines and a decision-making process for risk-informing regulatory activities in NMSS. The risk guidelines are one factor considered in this systematic decision-making process, but it also addresses other factors, including defense-in-depth and value-impact analysis. A guidance document describing this systematic process and the guidelines was completed in September 2004. This guidance has been modified to reflect subsequent comments. This completed the developmental phase of risk-informing.

In FY 2005, NMSS initiated Phase 3, the implementation and trial use phase, where the applicability of proposed risk-informed decision-making guidance will be tested in the course of selected ongoing NMSS activities. Due to resource limitations, the Risk Task Group has been disbanded, and no funding specifically for risk-informing is budgeted. Instead risk-informing will be carried out as a part of normal budgeted activities and as part of the NMSS continuous improvement process. Further refinement of the guidance based on lessons learned during trial uses will be coordinated 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-14 Effectiveness Strategic Plan Goal

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

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: Medium

Secondary Priority: Medium

SFPO and RES staff have initiated a spent fuel dry storage cask probabilistic risk assessment (PRA). This PRA study is intended to accomplish the following objectives: (a) provide a methodology to quantify the risks of dry cask storage of spent nuclear fuel and (b) apply the methodology to a specific cask design at a specific site. In February 2003, RES completed a draft pilot PRA on dry cask storage with a specific design. RES completed a significant revision to this report in January 2005, which includes more realistic analysis in response to peer reviewer comments. Additional revisions are being made in response to an NMSS request to increase the scope of the PRA to address additional comments and to improve the communication of risk insights to the public. The staff plans to present its findings to the Advisory Committee on Nuclear Waste in 2006. The draft study determined that a stainless steel welded canister with a concrete overpack poses a very low risk to the public.

This effort is part of the overall effort to develop a framework for incorporating risk information in the NMSS regulatory process. The methodology and results of the PRA will provide insights to support future risk-informed regulatory decisionmaking activities.

Project Considerations: This activity requires technical assistance and further development of analytical and computational methods. Completion of the analyses will help SFPO better communicate the realistic probabilities, consequences, and risks associated with a PRA for a specific design and site and the associated methods for analyzing risk.

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Define project scope and initiate pilot PRA (Phase I)			June 2000	RES/DRASP (NMSS/SFPO/TRD)
Conduct briefing on preliminary integrated risk results	November 2001		November 2001	RES/DRASP (NMSS/SFPO/TRD)
Complete pilot PRA and issue a preliminary report on integrated risk results	May 2002	June 2002	June 2002	RES/DRASP
Complete revised draft pilot PRA for peer review	October 2001	April 2003	February 2003	RES/DRASP
Complete another revised draft pilot PRA for peer review	August 2004	January 2005	January 2005	RES/DRASP
Conduct briefing on final pilot PRA for ACRS/ACNW	June 2003	September 2006		RES/DRASP (NMSS/SFPO/TRD)
Issue final pilot PRA as NUREG	2006	6 months after the ACNW briefing		RES/DRASP

EF-15 Effectiveness Strategic Plan Goal

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

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

Strategy 6: Minimize unnecessary regulatory or jurisdictional overlap.

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

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

Primary Priority: N/A

Secondary Priority: N/A

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

The Commission issued a staff requirements memorandum (SRM) on October 9, 2003, for this SECY paper. The Commission partly approved and partly disapproved the recommendation of the staff. The Commission does not want the staff to continue to pursue legislation at this time, because the Commission does not believe legislation will be approved by Congress. However, the Commission does want the staff to continue, as a low priority, to gauge the level of support with other Federal agencies and the States and explore other possible approaches to rationally treating these materials.

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

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

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

EF-16 Effectiveness Strategic Plan Goal **(Recommended for deletion since complete)**

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: N/A

Secondary Priority: N/A

Description of Activity:

The staff used the risk information in NUREG/CR-6642, along with supplemental records from the underlying database, in review ing the "Mallinckrodt Lessons Learned" and deciding whether to revise 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 improving 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 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 nonmedical 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

(This page intentionally left blank)

EF-17 Effectiveness Strategic Plan Goal

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

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

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

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

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

Primary Priority: N/A

Secondary Priority: N/A

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

Project Considerations: In September 2005, the staff established a working group to evaluate information obtained by NRC (after September 11, 2001) about security assessments, security inspections, and security concerns from previous NRC licensing actions that involved panoramic irradiators. The working group will present recommendation to the Petition Review Board in early 2006.

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

EF-18 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: Medium

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

The experience from guidance development was factored into development of the proposed rule. The new requirements will be given in a new section in Part 50, Section 50.69, “Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Plants.” The

staff completed preparation of the proposed rule package and sent it to the Commission in SECY-02-0176 (September 30, 2002). The proposed rule package included a draft regulatory guide (DG-1121) providing staff comments on and clarifications of the industry-proposed implementation guidance contained in draft Revision C of NEI 00-04 ("10 CFR 50.69 SSC Categorization Guideline"). A Commission briefing was conducted on November 21, 2002. The Commission's SRM dated March 28, 2003, directed the staff to publish the proposed rule for public comment. Proposed 10 CFR 50.69 was subsequently published on May 26, 2003, for a 75-day comment period, which was later extended by 30 days.

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

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

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

EF-19 Effectiveness Strategic Plan Goal

Implementation Activity: Develop a plan for making a risk-informed performance-based revision to 10 CFR Part 50 (Part 50) (RES/DRASP)

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

A staff requirements memorandum (SRM) was issued on May 9, 2005, from the Commission meeting held on Tuesday, April 5, 2005, on the subject of Briefing on RES Programs, Performance, and Plans. One item in this SRM states: "RES staff should work with NRR to develop a formal program plan to make a risk-informed and performance-based revision to 10 CFR 50 (Part 50), including revisions to the applicable Regulatory Guides, Standard Review Plans, or other guidance documents." In a September 14, 2005, SRM, the Commission directed the staff to develop an ANPR and to incorporate into the ANPR the formal program to risk-inform Part 50. The plan proposed by the staff involves creating a completely new risk-informed and performance-based revision to 10 CFR Part 50 that is technology-neutral. This new Part 53 is a continuation and advancement of work described in SECY-05-0006, "Second Status Paper on the Staff's Proposed Regulatory Structure for New Plant Licensing and Update on Policy Issues Related to New Plant Licensing." Based on the above SRMs, it is more appropriate to continue this work under EF-6, "Develop structure for new plant licensing."

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Hold public meeting to solicit stakeholder input	August 2005		August 2005	RES/DRASP
Issue plan to Commission	December 2005		December 2005 (1)	RES/DRASP

(1) Activities associated with plan to make a risk-informed performance-based revision to 10 CFR Part 50 have been incorporated into the work to “Develop structure for new plant licensing,” EF-6.

EF-20 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

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

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

(This page intentionally left blank)

EF-21 Effectiveness Strategic Plan Goal

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

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

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

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

Strategy 8: Make timely regulatory decisions.

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

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

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

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

Primary Priority: High

Secondary Priority: Medium

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

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

Selected Major Milestones and Schedules				
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**	**NRC Responsibility**
Forwarded to the EDO the annual SECY report on the status of the ASP Program and the SPAR Model Development Program.	September 2005		September 2005	RES/DRASP
Provide NRR and regional offices with semi-annual progress report for enhanced Revision 3 SPAR model accomplishments in support of the RASP	April 2006			RES/DRASP
Forward to the EDO the annual SECY report on the status of the ASP Program and the SPAR Model Development Program.	September 2006			RES/DRASP

EF-22 Effectiveness Strategic Plan Goal

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

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

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

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

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

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

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

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

Primary Priority: Medium

Secondary Priority: High

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

In SECY-01-0133, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)," and SECY-02-0057 (update to SECY-01-0133), the staff recommended rulemaking to change the technical requirements for the emergency core cooling systems (ECCS). The staff recommended separate rulemakings for proposed changes to (1) ECCS functional reliability requirements, (2) ECCS acceptance criteria, and (3) ECCS evaluation model requirements.

In July 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.

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

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

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

In response to the main provisions of the SRM (items 1, 2, 3 and 4), the staff prepared SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCAs) Break Size and Plans for Rulemaking on LOCAs With Coincident Loss of Offsite Power," in which the staff requested direction and additional guidance on policy issues that would facilitate resolution of identified technical issues. The technical issues included (1) the alternate break size selection metric, (2) appropriate limitations on what modifications would be allowed in a plant and how they could change the risk profile, (3) defense-in-depth considerations, and (4) the appropriate level of mitigative capability which should remain for breaks beyond the new design basis. The staff recommended finishing the review of the topical report and pilot exemption requests on LOCA-LOOP before initiating a LOCA-LOOP rulemaking plan. In April 2004 the BWROG submitted its topical report for NRC review. In May 2004, anticipating Commission direction on these issues, the staff established a 50.46 Steering Committee to direct and coordinate an expedited effort to issue a proposed rule.

The Commission approved the SECY-04-0037 recommendation on LOCA-LOOP that rulemaking be deferred until after the staff has completed its review of the BWROG topical report. The staff currently expects to complete review of the topical report by December 2006. Accordingly, if the staff concludes that if rulemaking is warranted, a LOCA-LOOP proposed rule could be completed no earlier than December 2007.

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

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

The proposed rule was issued for public comment on November 7, 2005. In response to a stakeholder request, the comment period was extended and closed on March 8, 2006. A report on seismic considerations for the transition break size was also posted for public comment on the NRC external Web site in December 2005. A public workshop to discuss the proposal was held on February 16, 2006.

In other matters related to SECY-04-0037, the Commission directed the staff to develop a rule for performance-based ECCS acceptance criteria applicable to cladding materials other than Zircaloy or ZIRLO™. The Chairman has recently approved funding for FY06-08 to begin this work, including verification testing of M5 and ZIRLO-clad high-burnup fuel rods. A Research Information Letter and NUREG/CR report are expected in June 2006 presenting the technical basis for the revised performance-based criteria.

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

(This page intentionally left blank)