Attachment 2

Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
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LIST OF ACRONYMS

ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee for Reactor Safeguards
ALARA	as low as reasonably achievable
ANPR	advance notification of proposed rulemaking
ANS	American Nuclear Society
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
ATWS	anticipated transient without SCRAM
BWR	boiling-water reactor
BWROG	Boiling Water Reactor Owners Group
CCF	common-cause failure
CFR	*U.S. Code of Federal Regulations*
CRGR	Committee to Review Generic Requirements
CRMP	configuration risk management program
DOE	Department of Energy
DPO	differing professional opinion
DSI	direction-setting issue
EPA	Environmental Protection Agency
EPIX	equipment performance and information exchange
EPRI	Electric Power Research Institute
ET	executive team
FAVOR	a probabilistic fracture mechanics code
FCSS	Fuel Cycle Safety and Safeguards
FSAR	final safety analysis report
FTE	full time employees
GL	generic letter
GQA	graded quality assurance
HRA	human reliability analysis
INPO	Institute of Nuclear Power Operations
IPEEE	individual plant examination - 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
LPSD	low power/shut down
LRS	low-risk significant
LT	leadership team
MACCS	MELCOR accident consequence code system
MOR	Monthly Operating Report
MSLB	main steam line break
NEI	Nuclear Energy Institute
NFPA	National Fire Protection Association
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRS	non-risk significant
NRR	NRC Office of Nuclear Reactor Regulation
OM	operation and maintenance
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
RBI	risk-based performance indicators
RES	NRC Office of Nuclear Regulatory Research
RG	regulatory guide
RI	risk-informed
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
SCSS	sequence coding and search system
SDP	significance determination process
SFPO	Spent Fuel Project Office (NMSS)
SGTAP	steam generator task action plan
SNM	special nuclear material
SPAR	standardized plant analysis risk
SRA	senior resident analyst
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
TTC	NRC Technical Training Center
USI	Unresolved Safety Issue
WOG	Westinghouse Owners Group

FOREWORD

The Nuclear Regulatory Commission's (NRC's) policy for implementing risk-informed regulation was expressed in the 1995 policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities. The policy statement says:

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

The Commission also said

> Given the dissimilarities 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 a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decisionmaking.

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

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

> To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the staff to develop a comprehensive strategy that includes but is not limited

> to objectives, goals, activities, and time frames for risk-informed regulation; specifies how the Commission expects to define the scope and implementation of risk-informed regulation; and identifies the manner in which it expects to continue the free exchange of operational information necessary to improve the quality and reliability of risk assessments.

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

Organization of the RIRIP

The RIRIP consists of two parts. Part 1 provides a general discussion of risk-informed regulation applicable to three of the primary strategic arenas. Part 1 first discusses the relevance of the RIRIP to the Agency's Strategic plan, and provides general guidelines for identifying "candidate" requirements, practices, and process that may be amenable to, and benefit from, an increased use of risk insights. Part 1 then provides a discussion of factors to consider in risk-informing the Agency's activities, including defense-in-depth, safety margins, the ALARA principle, and safety goals. Finally, Part 1 provides a general discussion of 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 arenas and is based on the Commission's strategic plan, with chapters on the Nuclear Reactor Safety arena, Nuclear Materials Safety arena, and Nuclear Waste Safety arena. Each chapter is organized around the strategic plan strategies relevant to risk-informed regulation in that arena. 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.

Certain implementation activities in the Reactor Safety, Materials Safety, and Waste Safety arenas may substantially differ in scope, form, and content. This is because the nature of the activities being regulated varies greatly, as does the availability of risk assessment methods. It should also be noted that this plan condenses the more detailed descriptions of staff activities in various Commission papers, program plans, and office operating plans.

PART 1. RISK-INFORMED REGULATION

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 would improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees. 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 judgment; (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.

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. The strategic plan sets strategic and performance goals and strategies for four strategic arenas: Nuclear Reactor Safety, Nuclear Materials Safety, Nuclear Waste Safety, and International Nuclear Safety Support. The agency has established four performance goals for the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas: (1) to maintain safety and protect the environment and the common defense and security, (2) to increase public confidence, (3) to make NRC activities and decisions more effective, efficient, and realistic, and (4) to reduce unnecessary regulatory burden. The strategic plan guides the

agency's initiatives to support risk-informed regulation by defining strategic goals, performance goals and measures, and "strategies." The RIRIP specifies ongoing or planned activities to implement strategic plan strategies for risk-informed regulation. It also specifies:

- 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 (see Figure 1).

2. Guidelines for Selecting "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 to resolve a question with respect to maintaining or improving the activity's safety?

(2) Could a risk-informed regulatory approach improve the efficiency or the effectiveness of the NRC regulatory process?

(3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden on the applicant or licensee?

(4) Would a risk-informed approach help to effectively justify a regulatory decision?

If the answer to any of the above is yes, proceed to additional considerations; if not, the activity is considered to be screened out.

(5) Are there data and/or analytical models of adequate quality to support risk-informing a regulatory activity or could they be developed?

If the answer to consideration 5 is yes, proceed to additional considerations; if not, the activity is considered screened out.

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

If the answer to consideration 6 is yes, proceed to additional criteria; if not, the activity is considered screened out.

(7) Do other factors limit the utility of implementing a risk-informed approach?

If the answer to consideration 7 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or screened out.

These screening considerations were developed by NMSS for use in the Materials and Waste arenas. The Coherence Team has adopted these criteria as part of the Coherence effort in the Reactor arena.

3. Factors To Consider in Risk-Informed Regulation

The NRC mission is to protect the public health and safety and the common defense and security in civilian applications of nuclear technology. 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, regardless of cost.

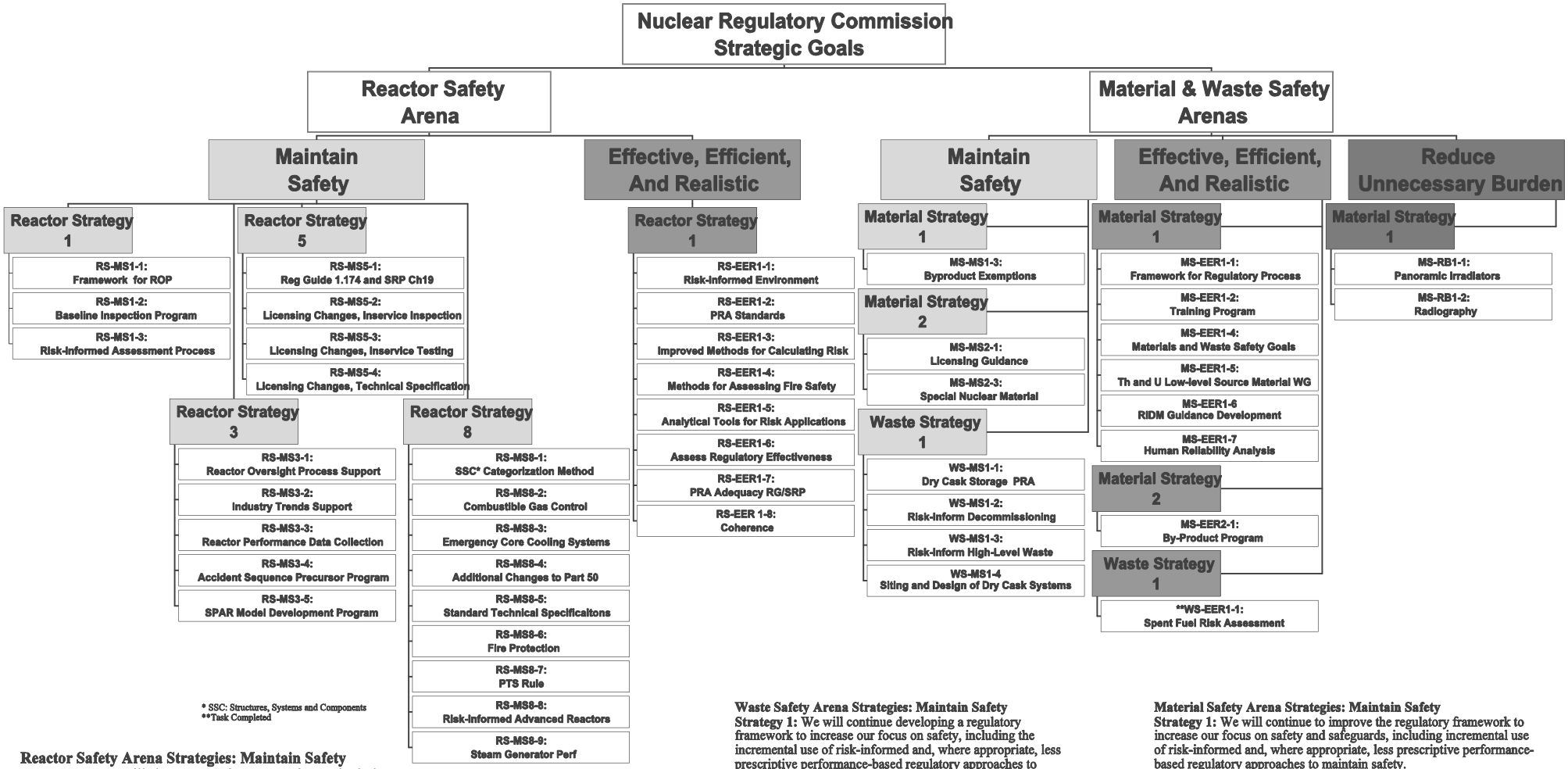
Since adequate protection is presumptively provided by existing regulations, the Commission has determined that, for nuclear power plants and fuel cycle facilities, proposed safety improvements beyond adequate protection should be adopted only if they provide “substantial” additional protection and the direct and indirect costs are justified. In the Nuclear Reactor Safety arena, regulatory analysis guidelines and backfit analysis guidelines have been developed for assessing a “substantial” improvement and calculating cost-benefit. In the Nuclear Materials Safety Arena, 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 (1) improving effectiveness, efficiency, and realism in agency decisions, practices, and processes, (2) increasing public confidence in the agency, and (3) reducing unnecessary regulatory burden on licensees.

To establish a consistent approach, the following factors (discussed in the paragraphs below) 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

Risk-Informed Regulation Implementation Plan



* SSC: Structures, Systems and Components
**Task Completed

Reactor Safety Arena Strategies: Maintain Safety
Strategy 1: We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.
Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.
Strategy 5: We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.
Strategy 8: We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive regulatory approaches to maintain safety.

Reactor Safety Arena Strategies: Effective, Efficient, and Realistic
Strategy 1: We will use risk information to improve the effectiveness and efficiency of our activities and decisions.

Waste Safety Arena Strategies: Maintain Safety
Strategy 1: We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.

Waste Safety Arena Strategies: Effective, Efficient, And Realistic
Strategy 1: We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.

Waste Safety Arena Strategies: Reduce Unnecessary Burden
Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

Material Safety Arena Strategies: Maintain Safety
Strategy 1: We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.
Strategy 2: We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework.

Material Safety Arena Strategies: Effective, Efficient, and Realistic
Strategy 1: We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.
Strategy 2: We will identify, prioritize, and modify processes based on effectiveness reviews to maximize opportunities to improve those processes.

Material Safety Arena Strategies: Reduce Unnecessary Burden
Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

- 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 factors of the deterministic approach. Among these factors are the fundamental safety principles of defense-in-depth, safety margins, the principle of "as low as reasonably achievable" (ALARA) radiation protection, and the agency's safety goals. The NRC has used these principles in its regulatory programs to maintain acceptable risk levels. They ensure that the nuclear industry 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 an element of the NRC's safety philosophy that employs 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 materials licensed 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 in the Reactor arena, defense-in-depth entailed "placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis accidents that represent the range of important accident sequences." For the Reactor arena, 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, 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.

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

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

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

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

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

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

<u>Safety Margins</u>

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.

In the Reactor arena, RG 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 in the reactor, materials, and waste arenas are evaluated to improve the focus on safety, regulations that require excessive safety margins will be candidates for change. To define the role that safety margins play in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

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

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

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

The ALARA Principle

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

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

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

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

Safety Goals

In general, a safety goal is useful to define the desired level of safety. In the Reactor arena, safety goals were 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 the Materials and Waste Safety arenas similar to the reactor safety goals, but taking the diversity of NMSS 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 relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. NUREG/BR-0303, "Guidance for Performance-Based Regulation," provides guidance to staff working on incorporating performance-based approaches to a wide range of regulatory issues. It 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 as to whether to provide licensees this choice is determined by the backfit rule and safety considerations. In risk-informing the agency's regulations, the staff may identify areas where mandatory requirements are warranted. The staff will evaluate proposed new requirements in line with existing guidance.

In 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, assessment (e.g., through use of performance indicators), and enforcement. The staff should consider the implications of risk-informed regulatory changes on regulatory oversight activities and ask about every risk-informed regulation:

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

Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees, include an accompanying regulatory analysis. In regard to relaxation of requirements, NUREG/BR-0058 states that a regulatory analysis

> should provide that level of assessment that will demonstrate with sufficient reasonableness that the two following conditions are satisfied:
>
> - The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented
> - The cost savings attributed to the action would be substantial enough to justify taking the action

As part of the staff's activities, the role of regulatory analysis in the evaluation of risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework. In this regard, in response to Commission concerns about bundling individual requirements in proposed risk-informed changes to 10 CFR Part 50 (Option 3) and 10 CFR 50.44 (Combustible Gas Control), the staff developed SECY-02-0255, "Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis."

4. Communication Plans

The agency recognizes that it must keep its staff, the public, and the nuclear industry informed about its regulatory activities. The staff has recognized the need to develop communication plans that will increase public confidence by setting out methods of conveying information about the agency's programs and activities to the public. Specifically, integrated arena-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 of NMSS prepared and submitted to the OEDO in December 2000 a communication plan for risk-informing regulatory activities in the Materials and Waste Safety arenas. 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. NRR and RES intend to develop a similar plan for the Reactor Safety arena.

In addition to these specific communication plans, RES has initiated a Risk Communication Project, coordinated with several other offices, which will develop guidance to improve the communication of risk insights and information to all NRC stakeholders.

The individual activity descriptions in Part 2 of the RIRIP indicate whether the staff has developed a communication plan specific to the activity or the general regulatory area.

5. Training Program

In the Nuclear Reactor Safety arena, the staff has already been given general training to increase its knowledge of and skills in probabilistic risk assessment. Training is available on a continual, as-needed basis. Additional training is being provided on certain risk-informed regulatory initiatives such as the revised Reactor Oversight Process. In the Nuclear Materials Safety and Nuclear Waste Safety arenas, the NRC's Office of Human Resources is identifying, developing, and implementing staff training to ensure that the staff is fully prepared for risk-informed regulation. Training activities are described in further detail in Part 2.

PART 2. RISK-INFORMED REGULATION IMPLEMENTATION ACTIVITIES

Part 2 of the RIRIP presents current risk-informed initiatives and activities in the Reactor Safety, Materials Safety, and Waste Safety arenas. Part 2 of the RIRIP has in two chapters: Chapter 1 addresses the Reactor Safety arena, and Chapter 2 addresses the Nuclear Materials and Waste Safety arenas. (For clarity, the Materials and Waste arenas are presented together since NMSS has primary responsibility for both.) At the beginning of each chapter is a summary describing the general plan for increasing the use of risk insights in regulatory activities.

Each chapter provides individual, detailed discussions of the implementation activities, including project management considerations and more detailed schedule and milestone information. Figure 1 shows the format of each activity discussion provided in Chapters 1 and 2.

To highlight activity interrelationships, a list is provided below of all of the RIRIP activities and any crosscutting activities identified by RES, NRR, and NMSS. For example, the first activity listed is RS-MS1-1, for which nine activities were identified as related (or crosscutting) in some way. Within each activity are critical path milestones that must be accomplished for that activity to be completed. The activity milestones are shown on the schedules (Gantt charts) associated with each of the activity descriptions presented in Chapters 1 and 2 of this part.

<u>Reactor Arena</u>

RS-MS1-1 Establish a framework for deciding on inspection, assessment, and enforcement action for nuclear power reactors that focuses on activities and systems that are risk-significant

- RS-MS1-2 Inspection Program
- RS-MS1-3 Assessment Process
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-4 ASP
- RS-MS3-5 SPAR Models
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

RS-MS1-2 Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process

RS-MS1-3 Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-2 Inspection Program
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-5 SPAR Models
- RS-EER1-6 Regulatory Effectiveness

RS-MS3-1 Reactor Oversight Process Support

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Reactor Performance Data Collection

RS-MS3-2 Industry Trends Support

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses
- RS-EER1-5 Maintain Analytical Tools
- RS-MS3-5 SPAR Models
- RS-EER1-6 Regulatory Effectiveness

RS-MS3-3 Reactor Performance Data Collection Program

- RS-MS1-3 Assessment Process
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-4 ASP Analyses
- RS-MS3-5 SPAR Models
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-7 PTS Rule
- RS-MS8-9 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-6 Regulatory Effectiveness

RS-MS3-4 Accident Sequence Precursor Program

- RS-MS1-1 Reactor Oversight Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-5 SPAR Models
- RS-EER1-6 Regulatory Effectiveness

RS-MS3-5 SPAR Model Development Program

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS5-1 Establish guidance for risk-informed licensing basis changes: Update RG 1.174 and SRP Chapter 19

- RS-MS5-2 Licensing Basis Changes: Inservice Inspection
- RS-MS5-3 Licensing Basis Changes: Inservice Testing
- RS-MS5-4 Licensing Basis Changes: Technical Specifications
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk

- RS-EER1-7 PRA Adequacy Reg Guide
- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-MS1-2 Decommissioning Regulatory Framework
- WS-MS1-3 High-Level Waste

RS-MS5-2 Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-7 PTS Rule Revision
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS5-3 Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS5-4 Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS8-1 Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS8-2 Change technical requirements of 10 CFR 50.44 (“Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors”)

- No crosscutting activities identified.

RS-MS8-3 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”)

- RS-EER1-2 PRA Standards Development
- RS-MS8-5 Standard Technical Specifications

RS-MS8-4 Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50

- RS-MS8-1 Special Treatment Requirements
- RS-EER1-7 PRA Adequacy Reg Guide

RS-MS8-5 Plan and implement risk-informed standard technical specifications (STS)

- RS-MS8-3 Emergency Core Cooling Systems
- RS-EER1-2 PRA Standards Development

RS-MS8-6 Fire protection for nuclear power plants

- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods

RS-MS8-7 Develop the technical basis to revise the PTS rule

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS5-2 Licensing Basis Changes: Inservice Inspection
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-8 PRA Review of advanced reactor applications

- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-9 Develop methods for assessing steam generator performance during severe accidents

- RS-MS3-3 Reactor Performance Data Collection
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-EER1-1 Creating a risk-informed environment

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

RS-EER1-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-3 Emergency Core Cooling Systems
- RS-MS8-4 Additional Changes to Part 50
- RS-MS8-5 Standard Technical Specifications
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

RS-EER1-3 Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking

- RS-MS3-5 SPAR Models
- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-7 PTS Rule Revision
- RS-MS8-9 Steam Generators
- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-4 Develop and apply methods for assessing fire safety in nuclear facilities

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS8-6 Fire Protection
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-5 Develop and maintain analytical tools for staff risk applications

- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-5 SPAR Models
- RS-MS8-9 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-7 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-6 Assess regulatory effectiveness using risk information

- RS-MS1-3 Assessment Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses

RS-EER1-7 Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.

- RS-MS3-5 SPAR Models
- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS5-2 Licensing Basis Changes: Inservice Inspection
- RS-MS5-3 Licensing Basis Changes: Inservice Testing
- RS-MS5-4 Licensing Basis Changes: Technical Specifications
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-MS1-1 Dry Cask PRA

RS-EER1-8 Develop a Coherence Program for the Reactor Safety Arena

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

Wastes and Materials Arenas

MS-EER1-1 Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process

- MS-EER1-2 NMSS Risk Training Program
- MS-EER1-4 Develop Risk Guidelines for Materials and Waste Arenas
- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-2 PRA Standards Development
- RS-EER1-7 PRA Adequacy Reg Guide
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development
- MS-EER1-7 Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications

MS-EER1-2 Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities

- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- MS-EER2-1 Multi-Phase Review of Byproduct Materials Program
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development
- MS-EER1-7 Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications

MS-EER1-4 Develop Risk Guidelines for the Materials and Waste Arenas

- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

MS-EER1-5 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

- No crosscutting activities identified.

MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

- MS-EER1-1 Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process
- MS-EER1-2 Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities
- MS-EER1-4 Develop Risk Guidelines for the Materials and Waste Arenas
- MS-EER2-1 Multi-phase Review of the Byproduct Materials Program
- WS-MS1-2 Incorporate Risk Information into the Decommissioning Regulatory Framework
- MS-MS1-3Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements

MS-EER1-7 Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications

- MS-EER1-1 Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process
- MS-EER1-2 Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities
- MS-EER2-1 Multi-phase Review of the Byproduct Materials Program

MS-EER2-1 Multi-phase Review of the Byproduct Materials Program

- MS-MS2-1 Materials Licensing Guidance
- MS-EER1-2 NMSS Risk Training Program

- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development
- MS-EER1-7 Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications

MS-MS1-3 Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements

- No crosscutting activities identified.

MS-MS2-1 Materials Licensing Guidance Consolidation and Revision

- MS-EER2-1 Review of Byproduct Materials Program

MS-MS2-3 Implementation of Part 70 Revision

- No crosscutting activities identified.

MS-RB1-1 Revise Part 36: Panoramic Irradiators (PRM-36-01)

- No crosscutting activities identified.

MS-RB1-2 Revise Part 34: Radiography (PRM-34-05)

- No crosscutting activities identified.

WS-MS1-1 Probabilistic Risk Assessment of Dry Cask Storage Systems

- WS-MS1-4 Revise Part 72: Siting/Design of Dry Cask ISFSIs
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide

WS-MS1-2 Incorporate Risk Information into the Decommissioning Regulatory Framework

- RS-MS5-1 RG 1.174 and SRP 19
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

WS-MS1-3 Incorporate Risk Information into the High-Level Waste Regulatory Framework

- RS-MS5-1 RG 1.174 and SRP 19
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

WS-MS1-4 Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs

- WS-MS1-1 Dry Cask PRA

Activity title and RIRIP activity identifier, which relates the activity to the Agency's strategic arenas, performance goals, and strategies described in the NRC Strategic Plan (NUREG-1614). *

Lead and support organization

Schedule date provided when the milestone first appeared in the RIRIP.

Project considerations may include relationships to other activities and organizational entities, critical path items, special training and communication requirements, and special resource requirements.

Related Agency performance goals and associated strategies.

Activity description

RS-MS8-7 Reactor Safety Arena

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

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

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 [illegible] rule in light of the results of subsequent extensive research on key technical issues [illegible] rule. Analyses performed as part of this research suggest that the agency [illegible] reduce unnecessary conservatism in the rule, while still maintaining safety.

The staff's approach for reevaluating the screening [illegible] 61 prescribes for reactor pressure vessel material characteristics is [illegible] SECY-00-0140, "Reevaluation of the Pressurized Thermal Shock Rule (10 CFR-[illegible]61), [illegible] Criterion," dated June 23, 2000, and subsequent periodic status reports [illegible] SECY-01-0045, SECY-01-0185, and SECY-02-0092, dated March 16, 2001, [illegible] May 30, 2002, respectively.

RES Priority: 5.8

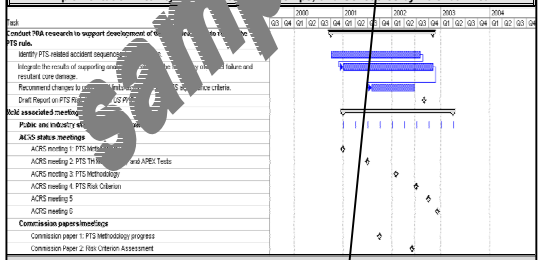
Reactor Safety Arena RS-MS8-7

Project Considerations: The timely completion of activities associated with this implementation activity requires close coordination, cooperation, and communication among numerous organizational units.

Selected Major Milestones and Schedules

Major Milestones	Original Target Date	Revised Date	Completion Date
Identify accident sequences significant to PTS for three representative plants	October 2001	August 2002	
Integrate the results of thermal/hydraulic, fracture mechanics, and sequence frequency analyses, using a probabilistic fracture mechanics code (FAVOR), to calculate the frequency of vessel failure and the resultant core damage.	January 2002	October 2002	December 2002
Draft report on recommend changes associated with PTS screening criteria.	Jan[illegible]2	November 2002	December 2002
Final report on recommend changes associated with PTS screening criteria.	S[illegible]		

Implementation Activity T[illegible]ships, and Schedules by Calendar Year



Major milestones and schedules.

Detailed schedule consistent with operating plans maintained by individual program offices.

Priority assigned by lead and supporting program offices through the Planning, Budgeting, and Performance Management (PBPM) process

Staff's current best estimated completion date.

*The first two letters of the activity identifier indicate the relevant strategic arena (RS for reactor safety, MS for materials safety, WS for waste safety). The remaining letters and the first number indicate the Agency performance goal (MS: maintain safety; PC: public confidence; EER: effectiveness, efficiency, and realism; RB: reduce unnecessary regulatory burden) and the particular strategy to which the activity is primarily related. The last number of the activity identifier is unique to the particular activity.

Figure 1
Layout and Format of Activity Descriptions

CHAPTER 1. REACTOR SAFETY ARENA

Sam Collins, Arena Manager

1.1 Introduction

The NRC has generally regulated nuclear reactors 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.

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 (NUREG-0800) for licensing reactors and some of the regulatory guides supporting NUREG-0800 provided review and evaluation guidance with respect to these probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. 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 (NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

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

For the last several years, NRC's work to expand the use of PRA in regulatory processes has been documented in the PRA Implementation Plan (see SECY-99-211). Many of the early actions focused upon the development of skills, tools, and infrastructure for the application of risk information.

In considering what areas in the Reactor 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 (discussed under the nuclear waste arena), and (3) advanced reactor designs.

The evolution of the staff's application of risk information to the regulation of nuclear reactors is briefly discussed below. Detailed information on specific staff activities, with respect to the Commission's strategic plan is provided later in this chapter.

Among the first examples of the agency's efforts to risk-inform reactor regulation are the appendices in 10 CFR Part 52 certifying the evolutionary standardized reactor designs. Part 52 requires that a PRA be performed for any future design and also that the design meet certain technical requirements to prevent and mitigate severe accidents. A rulemaking in the planning stage would further require that operators of standard design plants maintain a " living" PRA.

SECY-97-171 "Consideration of Severe Accident Risk in NRC Regulatory Decisions", discussed how severe accident risk had been considered in the past as well as areas where it might be for the future. For instance, the NRC promulgated new rules requiring plants to deal with accidents that were beyond the normal design basis (station blackout and anticipated transients without scram) on the basis of risk information. The regulatory analysis guidelines by which NRC makes decisions about whether requirements are cost-beneficial backfits also consider risk of severe accidents. As discussed in Part 1, the development of the safety goal policy was also a major step. Beginning in 1988, the staff also undertook a plan to consider severe accident risks for existing plants. This plan included several activities, including issuance of Generic Letter (GL) 88-20 asking licensees to conduct individual plant examinations (IPEs) to look for plant-specific vulnerabilities to severe accidents. Other activities considered containment performance and utility severe accident management programs.

With the enhanced capabilities to assess risk, 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 greater use of risk information in the regulatory process could be accomplished in a manner that maintained safety, improved safety focus, and reduced unnecessary burden. Thus, the staff is now focusing upon other activities, such as rulemaking, to offer voluntary options for licensees. These activities include both specific technical areas (e.g., fire protection) as well as broader changes such as the adjustment of special treatment requirements.

It should be noted that, where necessary, the staff has also added requirements as a result of risk information. For example, the maintenance rule (10 CFR 50.65) was recently modified to require licensees to assess and manage the increase in risk that may result from maintenance activities.

Reactor Safety Arena

Risk information is being used to focus staff activities with respect to inspection and enforcement and to adjust specific requirements on licensees. For example, the risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures, and components and to develop processes by which the risk significance of inspection findings could be determined. For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered. 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 upon both the significance of individual findings as well as 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 Reactor Safety Arena 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. Although a common prioritization scheme is currently being developed, the prioritization processes followed by NRR and RES management are not the same. However, the prioritization processes followed by NRR and RES management use the agency's strategic plan performance goals to prioritize office activities as part of the budget process. Those research programs identified in the RIRIP are rated with a score from 1-13.5, with 13.5 indicating highest priority. NRR prioritization scores range from 1-12, with 12 indicating highest priority. Because the scoring systems are not intended to numerically order the activities, it is important to note that more than one activity may have the same score. Staff activities are prioritized as they relate to maintaining safety; improving effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence. As with other staff activities, changes in priorities of the staff's risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities.

1.2. Description of Current Initiatives and Activities

Current initiatives and activities to risk-inform the regulatory applications of the Reactor Safety arena include the following:

RS-MS1-1 Establish a framework for deciding on inspection, assessment, and enforcement action for nuclear power reactors that focuses on activities and systems that are risk-significant

Reactor Safety Arena

RS-MS1-2	Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant.
RS-MS1-3	Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information
RS-MS3-1	Reactor Oversight Process Support
RS-MS3-2	Industry Trends Support
RS-MS3-3	Reactor Performance Data Collection Program
RS-MS3-4	Accident Sequence Precursor Analysis Program
RS-MS3-5	SPAR Model Development Program
RS-MS5-1	Establish guidance for risk-informed licensing basis changes: Update RG 1.174 and SRP Chapter 19
RS-MS5-2	Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection
RS-MS5-3	Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing
RS-MS5-4	Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications
RS-MS8-1	Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method
RS-MS8-2	Change technical requirements of 10 CFR 50.44 (“Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors”)
RS-MS8-3	Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”)
RS-MS8-4	Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50
RS-MS8-5	Develop risk-informed improvements to the standard technical specifications (STS)
RS-MS8-6	Fire protection for nuclear power plants

RS-MS8-7 Develop the technical basis to revise the PTS rule

RS-MS8-8 Develop the technical basis to support risk-informed review of advanced reactors

RS-MS8-9 Develop methods for assessing steam generator performance during severe accidents

RS-EER1-1 Creating a risk-informed environment

RS-EER1-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees

RS-EER1-3 Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking

RS-EER1-4 Develop and apply methods for assessing fire safety in nuclear facilities

RS-EER1-5 Develop and maintain analytical tools for staff risk applications

RS-EER1-6 Assess regulatory effectiveness using risk information

RS-EER1-7 Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.

RS-EER1-8 Coherence Program for Reactor Safety Arena

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

RS-MS1-1 Reactor Safety Arena

Implementation Activity: **Establish a framework for deciding on inspection, assessment and enforcement actions for nuclear power reactors that focuses on activities and systems that are risk-significant. (NRR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The basic approach under the oversight process is to monitor performance with respect to reactor safety cornerstones (initiating events, mitigation system performance, barrier integrity, and emergency preparedness), radiation safety (worker exposure and general public protection during routine operations), and security. Indicators that can be used to monitor performance against these cornerstones have been developed. NRC has also identified “inspectable areas” which relate to these cornerstones and for which performance indicators alone are not sufficient to monitor performance. NRC is also inspecting the performance indicator reporting process. The results and lessons learned from ROP implementation are documented in annual reports to the Commission.

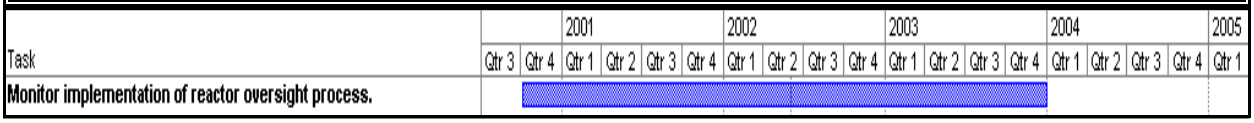
ROP-1	April 2000 - March 2001	SECY-01-0114
ROP-2	April 2001 - December 2001	SECY-02-0062
ROP-3	January 2002 - December 2002	SECY-03-0062
ROP-4	January 2003 - December 2003	

NRR Priority: 11

Project Considerations: The reactor oversight process was developed with input from a wide range of stakeholders. It was piloted with a subset of the reactors and the new program was implemented nationwide in April 2000. Lessons learned will be shared with NMSS in its efforts to improve the materials and waste regulatory framework.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Report on lessons learned from full implementation	June 2001		June 2001
Status report on lessons learned from implementation	March 2002		April 2002
Annual status report on ROP implementation	March 2003	April 2003	April 2003
Annual status report on ROP implementation	April 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant. (NRR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

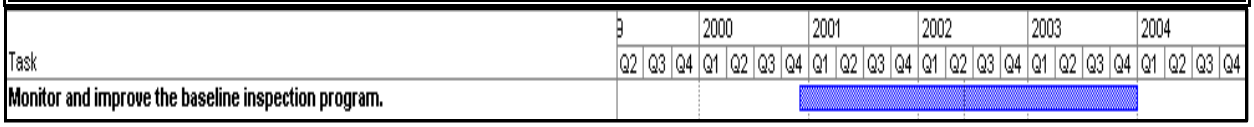
The risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures and components (risk matrices) and to develop processes by which the risk significance of inspection findings could be determined (significance determination process). For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered. Also, the staff used the results of previous experiences to ascertain how we have used risk significant issues in the past.

NRR Priority: 11

Project Considerations: The staff developed a self-assessment process to continue to refine and improve the reactor oversight process to incorporate lessons learned and future risk insights. The staff presented the results of its annual assessment of the ROP in SECY-03-0062 in April 2003.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Revise inspection procedures to incorporate lessons learned from initial implementation	January 2002		January 2002
Quarterly inspection procedure updates to incorporate lessons learned from ROP implementation	January 2003	June 2003	June 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The assessment process utilizes inspection and performance indicator results. Risk information is 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 (action matrix) to define the agency response, depending upon both the significance of individual findings as well as overall cornerstone performance. The notebooks used for the SDP will be improved in order to address challenges identified with the implementation of the SDP. The staff has developed SDP improvement strategies and an associated SDP Improvement Task Action Plan to provide for continued improvements in the timeliness, consistency, and usefulness of the SDP tools.

Performance is assessed by categorizing the indicators and inspection findings using significance thresholds to decide upon agency response. Depending upon the results in the various cornerstone areas, NRC will continue its baseline inspection, will inspect licensee corrective actions to deal with problem areas, will undertake additional inspections to focus upon the cause of the degraded performance, or if performance is unacceptable, the plant will not be permitted to operate until the problems are corrected.

NRR Priority: 11

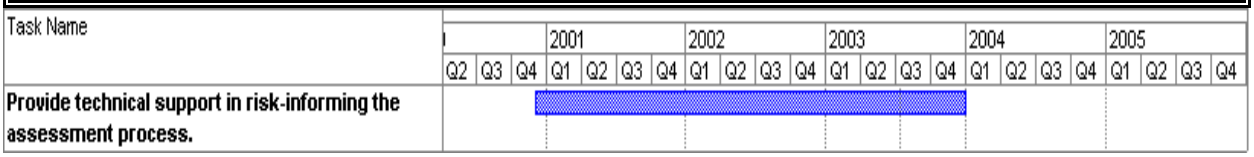
Project Considerations: The NRC has convened a task group to assess inspector training and qualifications in light of the reactor oversight program and other risk-informed initiatives. The recommendations of the task group have been incorporated into Inspection Manual Chapter IMC1245,"Inspector Qualification Program for the Office of Nuclear Reactor Regulation Inspection Program," dated April 4, 2002.

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

The mitigating systems performance index (MSPI) has been developed by NRC staff and industry, and is currently in the pilot program stage. Data collection has been completed and the staff is evaluating the results. The staff expects to determine the feasibility of MSPI by the end of October 2003.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Maintain and improve significance determination process notebooks	September 2001	October 2004	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS3-1 Reactor Safety Arena

Implementation Activity: Reactor Oversight Process (ROP) Support (RES)

Primary Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Under the Reactor Oversight Process (ROP) Support program, RES:

- Provides risk-informed improvements to the Significance Determination Process (SDP) by:
  - Independently verifying SDP inputs, results, and findings and comparing Accident Sequence Precursor (ASP) results to NRR's SDP findings.
  - Supporting shutdown and fire SDP improvements.
- Develops and pilots improved Performance Indicators (PIs) for the Reactor Safety Cornerstones (including thresholds) by:
  - Developing and piloting Mitigating Systems Performance Indicators (MSPIs).
  - Developing thresholds for the above PIs for use in a risk-informed regulatory framework.
- Links risk-informed operating experience to the inspection process.

Information from the ROP support program is used by NRR/DIPM/IIPB to:

- Verify that SDP findings are sound.
- Enhance the shutdown SDP.
- Evaluate MSPIs for pilot plants based on plant-specific thresholds using available Rev 3 SPAR models.

The MSPI will be used by NRR/DIPM/IIPB.

- Highlights of the MSPI development program include:
  - MSPI is being evaluated in a pilot program involving 20 nuclear power plants.
  - MSPI accounts for the unreliability and unavailability of six important mitigating systems at the plant.
  - MSPI balances component unavailability and unreliability consistent with the Maintenance Rule (10 CFR 50.65) and addresses a deficiency in current indicators that measure just unavailability.
  - MSPI accounts for plant-specific design features, as well as the plant-specific Probabilistic Risk Assessments (PRA).

RES Priority: 12.8
NRR Priority: 6.0

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the development and reporting of MSPIs. The MSPIs will utilize information obtained from: (1) inspection reports and Standardized Plant Analysis Risk (SPAR) models; (2) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, common-cause failure (CCF) studies, and special issue studies such as those addressing fire events and service water system events; and (3) operational data contained in Licensee Event Report (LER) databases, the Reliability and Availability Data System (RADS), the CCF database, and the Monthly Operational Report (MOR) database.

MSPIs will support the ROP assessment activities by providing direct measurements of the performance of risk-important safety features to determine whether safety is improving, deteriorating, or remaining constant. The supporting analyses and data systems needed to develop MSPIs will also be used by NRRs inspection staff in developing risk-informed inspection guidance and Significance Determination Process (SDP) evaluations, and by RES staff that use risk-important information to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Provide quarterly-update reports on comparison of ASP and SDP findings in support of ROP.	June 2002; September 2002; December 2002; March 2003		Complete
Draft guidance document for unreliability computation to support July 2002 PI pilot program public workshop.	June 2002		Complete
Pilot Plants — Determine plant-specific thresholds for the unreliability and unavailability indicators using available Rev 3 SPAR models.	September 2002		Complete
Provide pilot program support, including input to NRR Regulatory Information Summary	September 2002		Complete
For all plants — Determine plant-specific thresholds for the pilot program unreliability and unavailability indicators and prepare preliminary report.	September 2002		Complete
Prepare guidance document for technology transfer of RBPIs for shutdown to the NRR staff to enhance shutdown SDP.	September 2002		Complete
Prepare internal report on feasibility of developing containment PIs using SPAR models for LERF.	September 2002		Complete
Complete a final report on SDP/ASP differences	September 2003		
Prepare a draft report presenting the results of independent verification of MSPI values for the ROP pilot plants.	September 2003		

RS-MS3-2 Reactor Safety Arena

Implementation Activity: Industry Trends Support (RES)

Primary Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Under the Industry Trends Support program, RES:

- Provides trends for initiating events, systems reliabilities, components reliabilities, common-cause failures, and fire events
- Develops thresholds for the above trends for use in a risk-informed regulatory framework.
- Provides reactor operating experience information on systems, components, initiating events, CCF events, and fire events.

Industry Trends are used by:

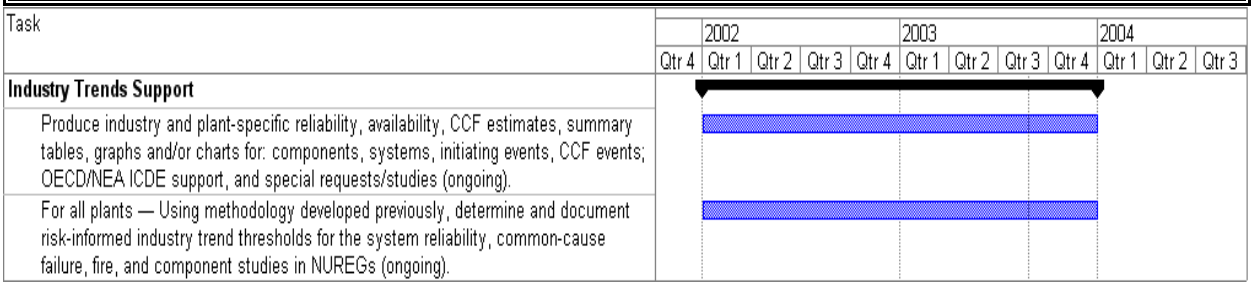
- NRR/DIPM/IIPB to: (1) monitor trends and report results to Congress: (2) monitor industry-wide safety performance and provide feedback to the ROP; and (3) enhance plant inspections of risk-important systems.
- NRR/DSSA/SPSB to support risk-informed technical reviews of proposed license amendments.
- RES/DSARE/REAHFB to evaluate the effectiveness of regulatory requirements.

RES Priority: 12.8

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the development and reporting of the risk significance of industry-wide operational events and data trends, as well as for conducting system reliability and related studies. The data for these studies is contained in LER databases, RADS, the CCF database, and the MOR database.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Produce industry and plant-specific reliability, availability, CCF estimates, summary tables, graphs and/or charts for: components, systems, initiating events, CCF events; OECD/NEA ICDE support, and special requests/studies.	Ongoing		Complete for FY2002
For all plants — Co-develop plan, methodology, and draft report documenting results determining risk-informed industry trend thresholds for ASP, ROP PIs, systems, and initiating events	September 2002	September 2002	Complete for FY2002
For all plants — Using methodology developed previously, determine and document risk-informed industry trend thresholds for the system reliability, common-cause failure, fire, and component studies in NUREGs.	Ongoing		Complete for FY2002
Prepare draft status report on risk-informed integrated industry initiating event indicator	September 2003		
Complete report on the integrated industry event indicator.	September 2003		
Provide NRR updated initiating event frequencies, system and component reliabilities, and common-cause failure statistics throughout FY 2002.	October 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS3-3 Reactor Safety Arena

Implementation Activity: Reactor Performance Data Collection Program (RES)

Primary Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Under the Reactor Performance Data Collection Program, RES maintains the following operating experience databases:

- Operational Events
  - Sequence Coding and Search System (SCSS) which contains information about events at nuclear power plants in a Web-based searchable system based on the sequence-coding of information in Licensee Event Reports (LERs).
  - The Monthly Operating Report (MOR) database which contains data on plant operations that are submitted by licensees via Monthly Operating Reports.
  - The Common-Cause Failures (CCF) database which contains data on risk-significant interactions, phenomena, and behavior in the design and operation of nuclear power reactors that originate from a common cause and were not previously recognized and analyzed.
  - The Fire Events database that compiles information on fire and smoke events that are listed in the SCSS database; the Equipment Performance and Information Exchange (EPIX) database maintained by the Institute of Nuclear Power Operations (INPO); the Fire Events Database maintained by the Electric Power Research Institute (EPRI); and the fire events database maintained by Nuclear Electric Insurance Limited (NEIL).
- Initiating Events (IEs)
  - The Initiating Events database which contains data and findings of the Initiating Events study along with updated information.
- Reliability and Availability Data
  - Reliability and Availability Data System (RADS) which estimates plant-specific and generic component-level reliability, and train level availability. RADS includes input from the Equipment Performance and Information Exchange (EPIX) database, which is maintained by the Institute of Nuclear Power Operations (INPO).
  - The systems database which contains data and findings of all systems reliability studies along with updated information.
  - The components database which contains data and findings of all components reliability studies along with updated information.
- Accident Sequence Precursors (ASP)
  - The Accident Sequence Precursor (ASP) events database which contains summary information on all the ASP events since 1969.

RES also has access to the following operating experience data maintained by NRR:

- Reactor Oversight Process Performance Indicators (ROP PIs)
- Mitigating Systems Performance Indicators (MSPIs) test data (In trial program)
- Performance Indicators developed by the disbanded NRC Office for Analysis and Evaluation of Operational Data (AEOD PIs)

RES also has access to the following operating experience databases maintained by the Institute of Nuclear Power Operations (INPO):

- Equipment Performance and Information Exchange (EPIX). (Data starting in 1997)
- Nuclear Plant Reliability Data System (NPRDS). (Data prior to 1997)
- World Association of Nuclear Operators (WANO). (Future use planned)

RES also has access to the following operating experience databases maintained by the Nuclear Energy Agency of the Organization of Economic Cooperation and Development (OECD/NEA):

- International Common-Cause Failure Data Exchange (ICDE) project.
- Swedish Nuclear Power Inspectorate (SKI) pipe failures database (SKI-Pipe)

RES Priority: 13.3

Project Considerations: The databases that are available through the RES Reactor Performance Data Collection Program are used to support:

- All RES/DRAA/OERAB analysis activities which include:
  - Plant-specific event analyses, such as ASP analyses using SPAR models.
  - Industry-wide analyses that are reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events.
  - The development of Risk-Informed Performance Indicators (RIPIs).
- NRR/DSSA/SPSB's risk-informed review of submittals, SDP evaluations, and resolution of generic safety issues.
- NRR/DIPM/IIPB's development of risk-informed inspection guidance.
- RES/DSARE/REAHFB's identification of ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.
- NRC's development of mitigating system PIs and associated pilot program for the ROP.

NRC licensees have access to CCF data.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Finalize the consolidated data collection and coding system functional requirements specifications.	February 2003		February 2003
Complete design of initial OERAB data and analysis web pages and begin 3-month trial period on the RES internal Web site.	June 2003		June 2003
Reduce coding in SCSS by eliminating coding of sequences.	June 2003		June 2003
Letter from INEEL documenting completion of the development of the consolidated data collection and coding system, including key features from SCSS and beginning of trial use period.	July 2003	August 2003	August 2003
Letter from ORNL certifying that the SCSS has been maintained and updated with the latest quarterly data available through 08/2003.	September 2003		

Letter from INEEL certifying that the consolidated data collection and coding system has been maintained and updated with latest quarterly data and the data are available for use in the industry trend program updates.	September 2003		
Final version of the OERAB data and analysis web pages completed.	September 2003		
Evaluation completed of artificial intelligence software for use in the consolidated data collection and coding system process.]	October 2003		
Consolidated data collection and coding system trial use period completed and fully implemented under a single contractor.	April 2004		
Discontinue SCSS at ORNL.	April 2004		
Memorandum from INEEL certifying that the consolidated data collection and coding system has been maintained and updated with latest quarterly data.	September 2004		

RS-MS3-4 Reactor Safety Arena

Implementation Activity: **Accident Sequence Precursor (ASP) Program (RES)**

Primary Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Under the Accident Sequence Precursor (ASP) Program, RES continues to review and evaluate operational experience to identify precursors to potential severe core damage sequences. This work includes:

- Documenting precursors.
- Categorizing precursors by plant-specific and generic implications.
- Providing a measure for trending nuclear plant core damage risk.
- Providing a partial check on failure combinations identified in PRAs and IPEs.

ASP analyses are used to support:

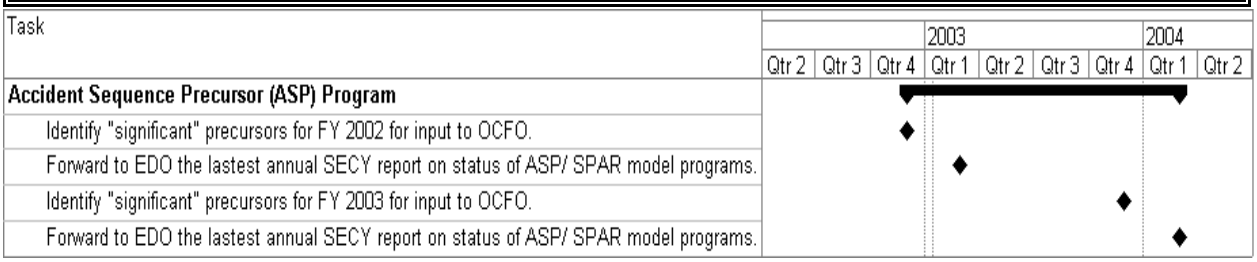
- Annual Performance and Accountability Report to Congress via the OCFO (significant precursors) and via NRR/DIPM/IIPB (adverse industry trend).
- Industry trends program by NRR/DIPM/IIPB.
- Annual SECY paper to the Commission on the status of the ASP program.
- Assessment by NRR/DSSA/SPSB of the risk associated with actual events to support senior management decisions to dispatch an AIT or IIT.
- NRR decisions to develop generic communications.
- Studies by RES/DSARE/REAHFB to determine the safety significance of potential regulatory issues.

RES Priority: 12.3

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary to support the ASP program. ASP analyses utilize information obtained from: (1) inspection reports and SPAR models; (2) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events; and (3) operational data contained in LER databases, RADS, the CCF database, and the MOR database.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Identify “significant” precursors for FY 2002 for input to OCFO.	December 2002		December 2002
Forward to EDO the latest annual SECY report on status of ASP/SPAR model programs.	March 2003		March 2003
Identify “significant” precursors for FY 2003 for input to OCFO.	December 2003		
Forward to EDO the latest annual SECY report on status of ASP/SPAR model programs.	March 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS3-5 Reactor Safety Arena

Implementation Activity: SPAR Model Development Program (RES)

Primary Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Under the Standardized Plant analysis Risk (SPAR) Model Development Program, RES is developing:

- Level 1, Rev. 3 Models.
- Level 2/LERF Models.
- Low Power/Shutdown (LP/SD) Models.

SPAR models are used to:

- Promptly assess the risk significance of events to identify regulatory actions by NRR and the Regions.
- Evaluate the significance of inspection findings in SDP Phase 3 by NRR and the Regions.
- Establish plant-specific thresholds for unreliability and unavailability PIs by RES and NRR.
- Support risk-informed technical reviews of proposed license amendments by NRR/DSSA/SPSB.
- Evaluate the effectiveness of regulatory requirements by RES/DSARE/REAHFB.
- Estimate the risk associated with operational events/conditions as part of the ASP program by OERAB.
- Perform regulatory analyses to resolve generic issues by RES.
- Support decisions to issue generic communications by NRR.

RES Priority: 13.3

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the SPAR models. SPAR models utilize data obtained from: (1) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events; and (2) operating experience data contained in the LER databases, RADS, the CCF database, the MOR database, and the ASP Events Database. In addition, SPAR models use information about plant design that is found in Final Safety Analysis Reports (FSARs), plant information books, and licensee's updated plant PRAs.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete all Revision 3i SPAR Models	November 2002		November 2002
Add uncertainty analysis capability to human reliability analysis (HRA) methodology; convert HRA methodology report to draft NUREG report and add section addressing LP/SD issues; and revise report to address peer review comments and issue NUREG.	December 2002	September 2003	
Document users' needs and results of evaluation of external events analysis methodology.	September 2003	TBD (Budget cut to $0K for FY2003)	
Document onsite QA reviews of Rev. 3i SPAR models completed from 09/2002 through 08/2003.	September 2003		
Document LP/SD and LERF SPAR models completed from 09/2002 through 08/2003.	September 2003		
Document completion of all onsite QA reviews of Rev. 3i SPAR models, revision of models to address review results, and certification of all 72 models as Rev. 3 SPAR models suitable for general use.	January 2004		

Issue draft program plan for developing prototype templates for external events and issue for internal peer review/evaluation by key users.	March 2004		
Issue draft program plan for developing a prototype SDP front-end interface for internal review.	March 2004		
Issue first prototype template for external events to key users for internal review/evaluation.	June 2004		
Issue prototype SDP front-end interface to key users for beta testing/evaluation.	June 2004		
Document LP/SD and LERF SPAR models completed from 09/2003 through 08/2004.	September 2004		
Revise first prototype template for external events to address review comments and issue final template and associated users' guidance.	September 2004		
Revise prototype SDP front-end interface to address review comments and issue final interface.	September 2004		

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RS-MS5-1 Reactor Safety Arena

Implementation Activity: **Establish guidance for risk-informed licensing basis changes: Update RG 1.174 and SRP Chapter 19 (RES & NRR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The PRA policy statement encourages greater use of PRA in all regulatory activities. One major activity is using PRA to support decisions to modify an individual plant's licensing basis. The staff prepared guidance documents to guide such risk-informed changes to a plant's licensing basis, as in requests for technical specification changes. The guidance describes acceptable means for assessing the nature and impact of licensing basis changes when the change request is supported by risk information. In being risk-informed, rather than solely based upon risk information, the NRC is retaining certain principles such as consistency with the defense-in-depth philosophy and maintenance of sufficient safety margins. The RG and the SRP were issued for public comment before being published.

NRC conducts periodic reviews of the Reg Guide and SRP to identify improvements. In the first revision of the documents since they were issued in July 1998, the following changes were made:

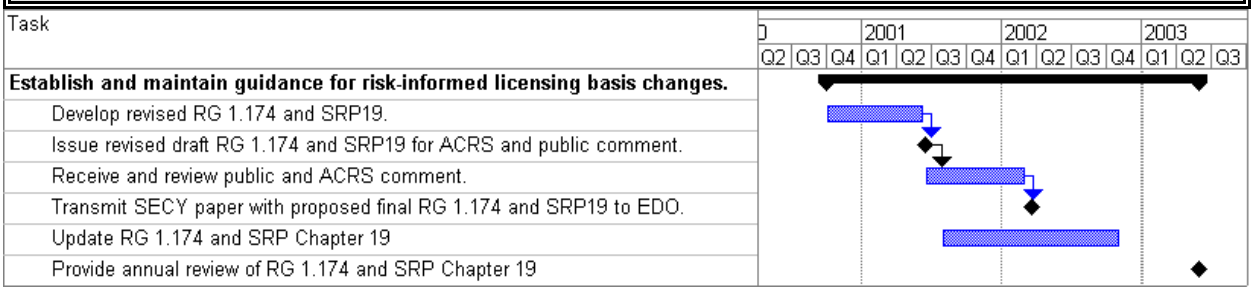
1. Risk related information may now be requested if new, unforeseen hazards emerge or prospects increase substantially for known hazards.
2. Indication was provided of on-going staff discussions on the effect of increases to fuel burnup/power level and changes to mixed-oxide fuel on risk metrics, such as large early release frequency.
3. Miscellaneous clarifications to LERF definition and reference to emerging industry PRA standards, e.g., ASME/ANS consensus standards.

RES Priority: 10.5
NRR Priority: 6.0

Project Considerations: The staff guidance concerning risk-informed licensing basis changes is influenced by insights derived through the development of PRA standards, the development of PRA methods, and insights from IPEs, IPEEEs, and other PRAs.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Update RG 1.174 and SRP Chapter 19	August 2001	December 2001	November 2002
Provide annual review of RG 1.174 and SRP Chapter 19	June 2003	June 2003	June 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS5-2 Reactor Safety Arena

Implementation Activity: **Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection (NRR & RES)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The NRC issued RG 1.178 and standard review plan Section 3.9.8 in September 1998. These documents provide guidance to licensees and staff regarding risk-informed inservice inspection (RI-ISI) programs for piping systems. The staff approved two industry topical reports on RI-ISI methodology. The Westinghouse Owners Group (WOG) methodology was approved in December 1998 and the Electric Power Research Institute (EPRI) methodology was approved in October 1999.

NRC staff activities include participation in the American Society of Mechanical Engineers (ASME) code development process. In this capacity, the staff has been involved in the review of the RI-ISI code Cases N-560, N-577, and N-578 and Appendix X. Staff activities also include continuing discussions and meetings with the industry to discuss and resolve issues such as the minimum ASME Class 1 sample size and extension of the RI-ISI methodology to the break exclusion region piping.

According to the information provided by Nuclear Energy Institute (NEI), 86 plants (units) are expected to implement RI-ISI programs by the end of 2003. The NEI also indicated that of the 86 RI-ISI submittals, 61 would be based on the EPRI methodology and 25 would be based on the WOG methodology. As of the end of May 2003, 69 plants have submitted their RI-ISI programs. The staff has approved 60 programs and the remaining 9 programs are currently under review.

The staff has established a schedule for the update of RG 1.178 and SRP 3.9.8. The staff intends to redraft the RG and SRP section, issue them for public and ACRS comment, and update/finalize the documents based on comments received. The process is expected to be completed by September 2003.

NRR Priority: 10.0
RES Priority: 10.5

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue final Inservice Inspection RG 1.178 and SRP Chapter 3.9.8	December 2001	September 2003	

RS-MS5-3 Reactor Safety Arena

Implementation Activity: Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The NRC staff prepared RG 1.175 and Section 3.9.7 to the Standard Review Plan to provide guidance for the establishment of risk-informed inservice testing (RI-IST) programs for pumps and valves at nuclear power plants. Several licensees are implementing the RI-IST program guidance in whole or in part. Additional experience regarding the application of risk insights to IST programs is being obtained by the staff. For example, the staff granted a risk-informed exemption request submitted by the licensee of the South Texas Project affecting special treatment requirements of low-risk and non-risk significant safety related nuclear components (including exemption from prescriptive inservice testing requirements). Also, the staff is developing a proposed rule (10 CFR 50.69) that would allow risk insights to be applied in reducing the special treatment requirements in 10 CFR Part 50 for structures, systems, and components that are categorized as being of low risk significance. In addition, the American Society of Mechanical Engineers is updating the *Code for Operation and Maintenance of Nuclear Power Plants* (OM Code) and applicable Code Cases to allow further use of risk insights in the inservice testing of pump and valves. The staff will review its current guidance for the establishment of RI-IST programs following the receipt of additional experience with these initiatives to determine if it is appropriate to update the RI-IST program guidance. In addition, the staff will continue to review RI-IST relief requests to ensure that they are consistent with the guidance established in RG 1.174.

NRR Priority: 10.0
RES Priority: 10.5

Project Considerations: The staff will soon issue a Regulatory Guide that will endorse the ASME risk-informed code cases (see activity RS-EER1-2). This will allow licensees to implement RI-IST programs without prior staff approval and may obviate the need to revise RG 1.175 and the related SRP sections.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue revision for public comment to Inservice Testing Regulatory Guide to reflect risk-informed Part 50, Option 2 rulemaking activities and experience gained with implementation of RI-IST programs and ASME risk-informed code cases	March 2002	TBD	

RS-MS5-4 Reactor Safety Arena

Implementation Activity: **Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications (NRR & RES)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Plant-specific licensing actions using the risk-informed guidance on technical specifications (TS) have been processed in the area of relaxations of allowed outage times for particular SSC.

Revision of RG 1.177 can proceed with the recent approval of Revision 1 to RG 1.174. The staff's activities related to risk-informing TS include several other initiatives discussed under another activity (see item RS-MS8-5).

NRR Priority: 10.0
RES Priority: 10.5

Project Considerations: Resolution of issues such as reaching a common understanding of defense-in-depth and safety margin are critical before the revision to RG 1.177 can be completed. These issues are being resolved in the staff's coherence program (see item RS-EER1-8.)

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue revision for public comment to Technical Specifications RG 1.177 and SRP Chapter 16.1 to reflect update of RG 1.174 and SRP Chapter 19	March 2002	September 2004	

RS-MS8-1 Reactor Safety Arena

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

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce Unnecessary Regulatory Burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The Commission decided in 1998 to consider promulgating new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations for power reactors. Special treatment may be defined as current requirements imposed on structures, systems, and components that go beyond industry-established requirements for equipment classified as "commercial grade" that 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 interested 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.

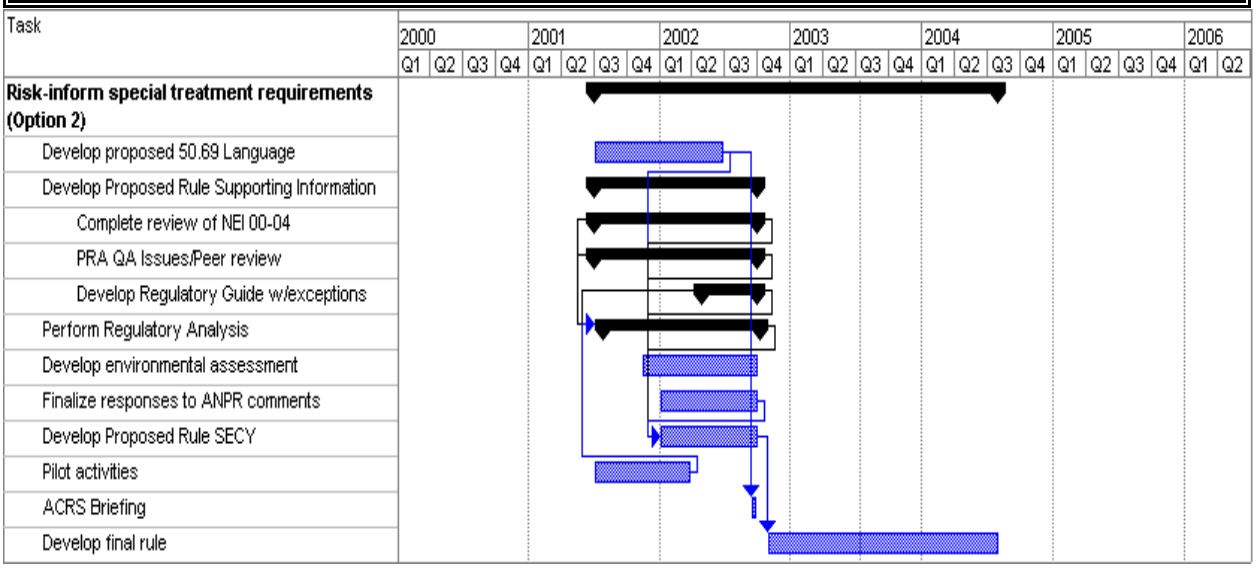
The experience from guidance development was factored into development of the proposed rule. The new requirements would be contained in a new section in Part 50, called section 50.69 Risk-Informed Categorization and Treatment of Structures, Systems and Components. The staff has completed preparation of the proposed rule package, which was sent to the Commission in SECY-02-0176 (September 30, 2002). The proposed rule package includes a draft regulatory guide (DG-1121) providing staff comments and clarifications on 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 issued 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.

NRR Priority: 8

Project Considerations: The staff has developed draft rule language and is working with the industry on NEI 00-04 implementation guidance. Challenges include addressing the issue of PRA quality and providing clear rule requirements.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target**	**Revised Date**	**Completion**
Rulemaking			
Proposed Rule	August 2001	September 2002	September 2002
Final Rule	December 2002	June 2004	
Pilot reviews			
Complete review of owners groups' pilot	June 2001	October 2001	March 2002
NEI Guidance review			
Staff completes review of categorization	June 2001	July 2002	August 2002

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Change technical requirements of 10 CFR 50.44 ("Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors") (NRR & RES)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden*.

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998, the staff proposed three options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. The purpose of one of these options (Option 3) was to identify possible changes to specific technical requirements in Part 50, to evaluate the feasibility of such changes, and, upon approval of the Commission, to change those requirements via the NRC's rulemaking process. The Commission approved the staff's proposal in a June 8, 1999, Staff Requirements Memorandum (SRM). The staff provided its more detailed plan and schedule for the identification and evaluation phases of the Option 3 work in SECY-99-264, "Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50," dated November 8, 1999. The Commission approved proceeding with the plan in a February 3, 2000, SRM.

The staff concluded that it is feasible to change the technical requirements of 10 CFR 50.44, as discussed in SECY-00-0198, and the Commission approved making the change via the rulemaking process in a January 19, 2001, SRM. In response to the January SRM, SECY-01-0162, dated August 13, 2001, recommended revision of existing hydrogen control regulations rather than developing a voluntary alternative and the establishment of Generic Issue 189 to assess the costs and benefits of possible additional hydrogen control requirements for PER ice condenser and BWR Mark III containment designs. On December 31, 2001, the Commission approved the staff's proposal and requested that the staff explain why installing passive autocatalytic recombiners would not pass a cost benefit test. On May 13, 2002, the staff's proposed rule package (SECY-02-0080) was provided to the Commission. This version of the rule eliminated the need for design basis combustible gas controls and realigned the regulatory treatment of oxygen and hydrogen monitoring systems. The proposed rule was published in the *Federal Register* on August 2, 2002 with a 75-day comment period. Comments have been evaluated and a final rule has been prepared. The ACRS and the CRGR have both reviewed and approved the final rule. The final rule was provided to the Commission on July 24, 2003.

RES Priority: 0.0
NRR Priority: 8.0

Project Considerations: As the first rule using the framework document developed for identifying and assessing candidate Part 50 changes, the development of schedules and resource requirements was subject to large uncertainties. Future changes to Part 50 are expected to be more resource efficient. Nevertheless, the framework proved to be very useful to the process of risk-informing 10 CFR 50.44.

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Proposed rulemaking to change 50.44 (NRR) to Commission	January 2002	May 2002	May 2002
Final rulemaking to Commission (NRR)	June 2003	July 2003	July 2003

RS-MS8-3 Reactor Safety Arena

Implementation Activity: **Change technical requirements of 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors" (NRR & RES)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden*.

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 10CFR50.46 (ECCS Acceptance Criteria) and SECY-02-0057 (update to SECY-01-0133), the staff recommended changes to the technical requirements for the Emergency Core Cooling System via the rulemaking process. The staff recommended that separate rulemakings be pursued for proposed changes to: 1) ECCS functional reliability requirements, 2) ECCS acceptance criteria, and 3) ECCS evaluation model requirements.

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

On July 31, 2002, the staff produced a technical report to support the development of a possible risk-informed alternative to GDC 35, the ECCS functional reliability requirements. The report recommended that the staff eliminate, on a generic basis, the ECCS design requirement for consideration of an assumed LOOP coincident with large, and possibly medium, LOCAs based on LOCA frequency and conditional LOOP probability estimates.

On March 31, 2003, the Commission issued an SRM on SECY-02-0057 with the following:

- Complete technical work on LOCA frequency estimation by March 31, 2004

2. Prepare proposed rule to allow for a risk-informed alternative to the present maximum break size by March 31, 2004
3. Prepare proposed rule with a performance-based approach to meeting ECCS acceptance criteria (by March 31, 2006).

4. Proceed with rulemaking to risk-inform ECCS functional reliability requirements in GDC 35 and thus relax the current requirement for consideration of a large break LOCA with a coincident LOOP by July 31, 2004.
5. Pursue a broader change to the single failure criterion and inform the Commission of its findings by July 31, 2004.

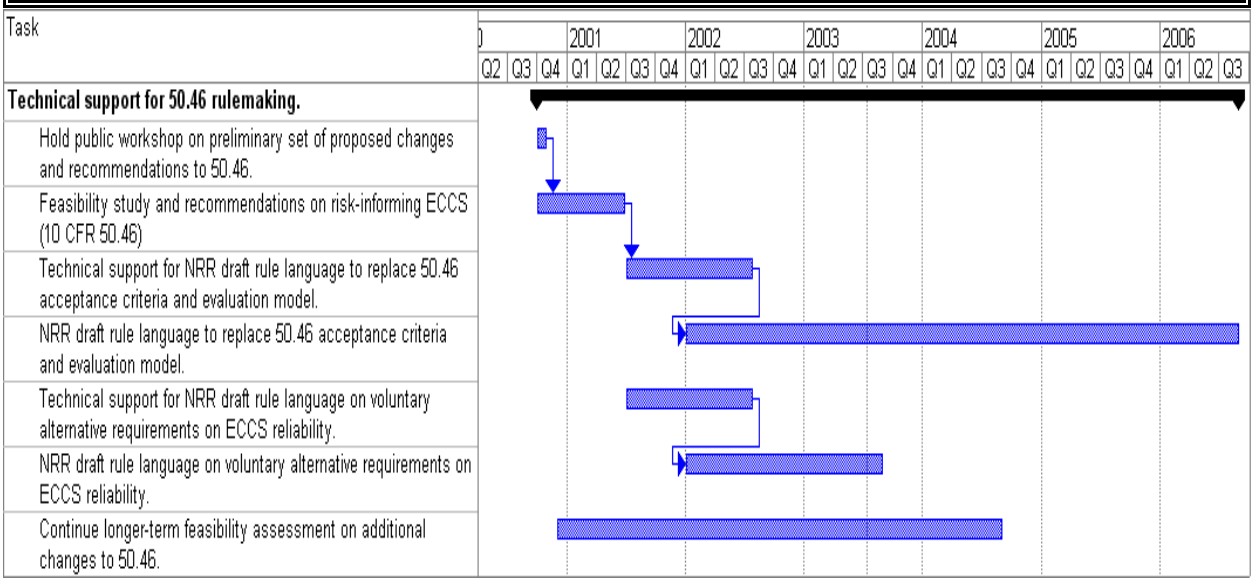
Finally, the Commission disapproved the recommendation to revise Appendix K and to instead require future applicants as well as those who seek to use the voluntary alternatives above to use best-estimate models.

RES Priority: 12.3
NRR Priority: 6.0

Project Considerations: The aggressive schedule established by the SRM for item 1 is absorbing significant rulemaking resources. Assessment of the impact on the budget and schedule is continuing.

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Develop technical basis for rule change: acceptance criteria and evaluation model requirements	July 2002		July 2002
Develop draft rule language for an option to replace current ECCS acceptance criteria	12 months after SRM	March 2006	
Develop technical basis for rule change: (1) optional/voluntary alternate plant-specific ECCS functional reliability requirements (2) optional/voluntary alternate generic ECCS functional reliability requirements	April 2002 April 2002	 July 2002	May/July 2002 July 2002
Develop draft rule language on voluntary alternative requirements to ensure ECCS functional reliability commensurate with the frequency of challenge	12 months after SRM		
Conduct feasibility assessment of additional changes to 50.46, including rigorous analysis of LOCA frequencies	July 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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RS-MS8-4 Reactor Safety Arena

Implementation Activity: Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50 (RES)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden*.

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998, the staff proposed three options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. The purpose of one of these options (Option 3) was to identify possible changes to specific technical requirements in Part 50, to evaluate the feasibility of such changes, and, upon approval of the Commission, to change those requirements via the NRC's rulemaking process. The Commission approved the staff's proposal in a June 8, 1999, Staff Requirements Memorandum (SRM).

The staff provided a more detailed plan and schedule for the identification and evaluation phases of the Option 3 work in SECY-99-264, "Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50," dated November 8, 1999. The Commission approved proceeding with the plan in a February 3, 2000 SRM.

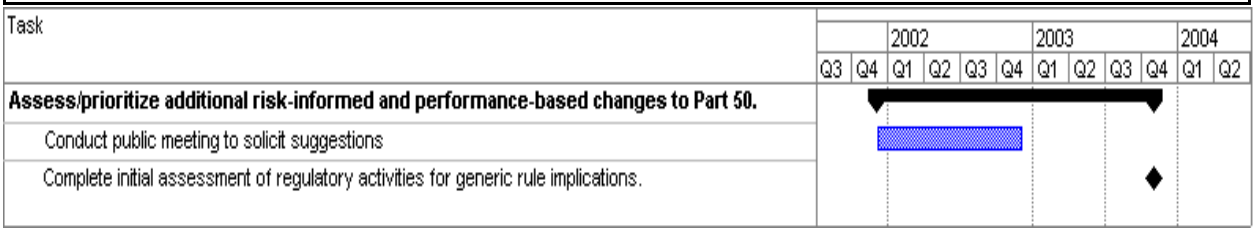
Additional input was reported in SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)," dated March 29, 2002. An SRM was issued on March 31, 2003, in response to the SECY directing the staff to proceed with rulemaking on 50.46 in a variety of areas including: redefinition of the large break LOCA, relaxation of LOCA-LOOP requirements of GDC 35, and a re-examining the single failure criteria. A public workshop was held on June 9, 2003, to provide the staff's understanding of the SRM and to obtain stakeholder feedback. Additional workshops are planned.

The staff has thus concluded that it is feasible to change the technical requirements of 10 CFR 50.44 and 50.46. At a future date, the staff also plans to initiate work on risk-informing 10 CFR Part 50, Appendix G, "Fracture Toughness Requirements," in conjunction with the work to risk-inform the pressurized thermal shock requirements. The staff is also currently assessing several regulatory activities and programs in order to assess their inter-related internal coherence and to identify any generic rule implications.

RES Priority: 12.0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Provide recommendations and feasibility report to Commission on other Part 50 changes	June 2001		July 2001
Conduct public meeting to solicit suggestions	December 2001	December 2002	December 2002
Complete initial assessment of regulatory activities for generic rule implications.	April 2003	July 2003	July 2003
Provide recommendations and feasibility of changes to other rules	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS8-5 Reactor Safety Arena

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

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security.*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

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

Proposals for risk-informed improvements to the STS are judged based on their ability to maintain or improve safety, the amount of unnecessary burden reduction they will likely produce, their ability to make NRC's regulation of plant operations more efficient and effective, the amount of industry interest in the proposal, and the complexity of the proposed change. The staff is re-evaluating the priorities for its review of risk-informed technical specification initiatives. The staff intends to follow the process 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 these improvements to the STS.

The industry and the staff have identified eight initiatives to date for risk-informed improvements to the STS. They are: 1) define the preferred end state for technical specification actions (usually hot shutdown for PWRs); 2) increase the time allowed to delay entering required actions when a surveillance is missed; 3) modify existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk); 4) replace the current system of fixed completion times with reliance on a configuration risk management program (CRMP); 5) optimize surveillance frequencies; 6) modify LCO 3.0.3 actions to allow for 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.

NRR Priority: 9.0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Initiative 1 - Write safety evaluation for CE PWRs, BWRs	June 2002	September 2002	September 2002
Initiative 1 - Write safety evaluation for CE STS: Approve TSTF-422 and make available via CLIIP	September 2003		
Initiative 2 - Completed			
Initiative 3 - Write safety evaluation for all plants	June 2002	August 2002	August 2002
Initiative 3 - Complete Standard Technical Specifications (STS) changes and make available via CLIIP	April 2003		April 2003
Initiative 6 - Write safety evaluation for CE PWRs	April 2003	June 2003	June 2003
Initiative 4 - Perform acceptance review and issue RAI questions on Risk Management Guide	September 2003		
Initiative 4 - Perform acceptance review and issue RAI questions in TSTF-424 (CE pilot)	December 2003		
Initiatives 5, 7, & 8	TBD		

RS-MS8-6 Reactor Safety Arena

Implementation Activity: Fire protection for nuclear power plants. (NRR)

Primary Performance Goal: *Maintain Safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Subactivity 1: **Voluntary alternative to NRC existing fire protection regulations**
The staff worked with the National Fire Protection Association (NFPA) to develop an alternative performance-based risk-informed fire protection standard for nuclear power plants. This standard, NFPA-805, was issued in April 2001. The staff published a proposed rule on November 1, 2002. A final rule is expected to be published in 2004. The staff is working with the industry to develop implementing guidance for NFPA 805 that will be endorsed by the NRC in a regulatory guide.

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-based post-fire safe shutdown methodology documents. These two documents have been combined into one document which provides a means of determining the potential risk for associated circuit failure during a postulated fire as a part of the safe shutdown analyses. NEI has completed a series of fire tests which provided insights to electrical cable performance and subsequent failures during a thermal insult.

NEI also assembled and completed the work of an Expert Panel to evaluate the test results. This work was published by EPRI in May 2002 as "Spurious Actuation of Electrical Circuits due to Cable Fires." (EPRI Report #1006961) NEI submitted NEI 00-01, "Guidance for Post-Fire Safe Shutdown Analysis," Draft Revision, D to the staff in October 2002. The staff is reviewing the document and will submitted their comments to NEI in December 2002. An ACRS Fire Protection Subcommittee was held to discuss this topic in June 2002.

Brookhaven National Laboratory (BNL), under contract to NRR, is completing a NUREG/CR on Post-Fire Safe-Shutdown Circuit Analysis. This report will consolidate existing information and offer Risk-Insights into the issue. A draft revision 1 of the NUREG/CR was released for public comment in April 2003.

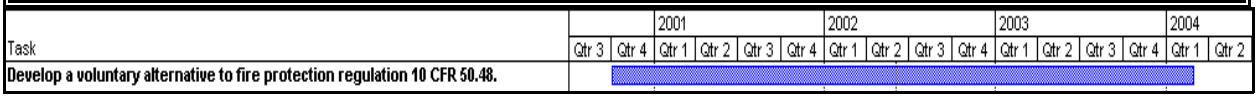
In February 2003, NRR held a facilitated workshop to discuss Risk-Informing the Post-Fire Safe-Shutdown electrical circuit inspections. The purpose of this workshop was to exchange information with our stakeholders concerning risk-informing the inspections. The staff has completed a draft RIS to discuss risk-informing this process, which is available for public comment. The staff is currently revising the inspection procedure, and another public workshop is scheduled for October 15-16, 2003 to discuss how the associated circuit inspections will be risk-informed.

NRR Priority: 6.0

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**
Publish proposed rule	October 2001	July 2002	November 2002
Issue final rule	April 2002	February 2004	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS8-7 Reactor Safety Arena

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

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

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.

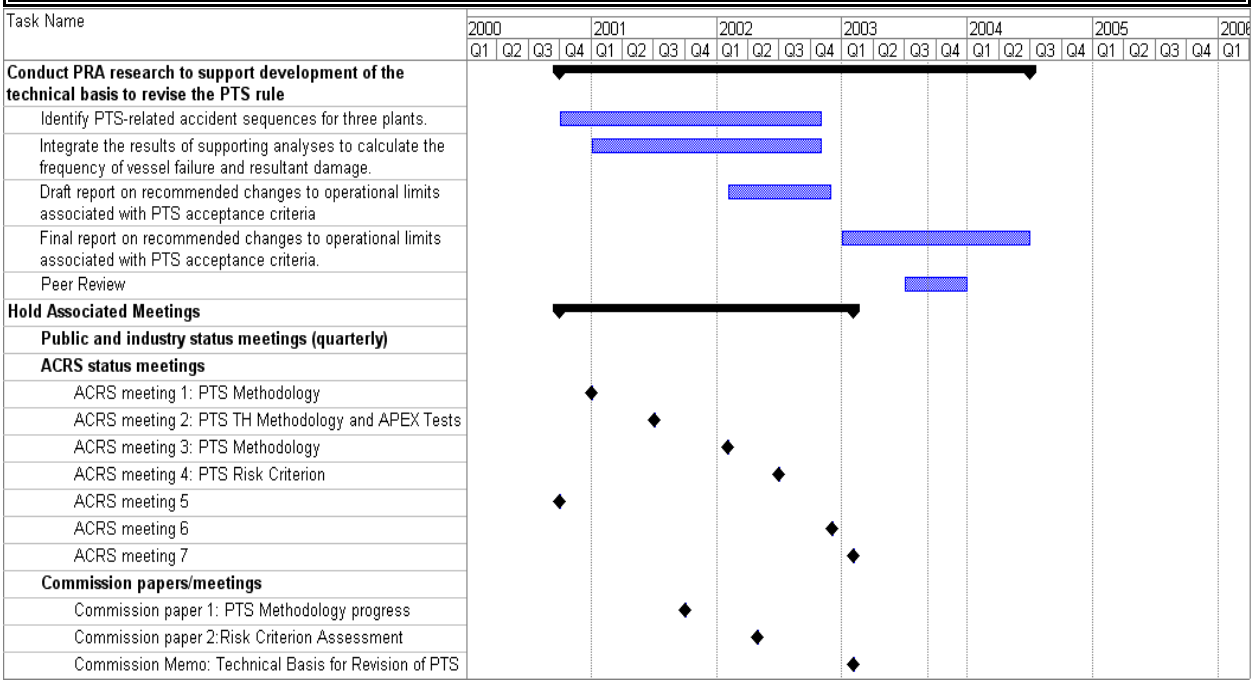
The staff's approach for reevaluating the screening criteria that 10 CFR 50.61 prescribes for reactor pressure vessel material characteristics is described in SECY-00-0140, "Reevaluation of the Pressurized Thermal Shock Rule (10 CFR 50.61) Screening Criterion," dated June 23, 2000, and subsequent periodic status reports identified as SECY-01-0045, SECY-01-0185, and SECY-02-0092, dated March 16, 2001, October 5, 2001, and May 30, 2002, respectively. A Draft Report integrating sequence frequency, thermal/hydraulic, and fracture mechanics analyses (using the probabilistic fracture mechanics code FAVOR) to calculate the frequency of vessel failure due to PTS was issued December 31, 2002. This report also presented the bases for possible changes to the PTS Rule.

RES Priority: 10.0

Project Considerations: The timely completion of activities associated with this implementation activity requires close coordination, cooperation, and communication among numerous organizational units.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Identify accident sequences significant to PTS for three representative plants	October 2001	October 2002	October 2002
Integrate the results of thermal/hydraulic, fracture mechanics, and sequence frequency analyses, using a probabilistic fracture mechanics code (FAVOR), to calculate the frequency of vessel failure and the resultant core damage.	January 2002	October 2002	December 2002
Draft report on recommended changes associated with PTS screening criteria.	January 2002	November 2002	December 2002
Final report with detailed description of PRA analysis methods and results for peer review	October 19, 2003		
Peer review of the Final Report on recommended changes in PTS screening criteria.	June 2003	December 31, 2003	
Commission Paper on recommending rulemaking to implement changes in PTS screening criteria.	TBD		
Final report on recommended changes associated with PTS screening criteria.	September 2003	June 30, 2004	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-MS8-8 Reactor Safety Arena

Implementation Activity: PRA Review of Advanced Reactor Applications (RES &NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

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. The plan has been implemented. Work has commenced on the generic PRA aspects for advanced reactors, as well as on design-specific reviews, e.g., ACR-700. The PRA is expected to interact with work in other areas related to advanced reactors, such as thermal/hydraulics (success criteria), and severe accident progression (accident sequence and source term identification).

NRR Priority: Not yet prioritized
RES Priority: 11.8

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
TBD			

RS-MS8-9 Reactor Safety Arena

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

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

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 100 siting requirements. Severe accident tube ruptures, in which a tube rupture either initiates the accident or occurs during the accident, can result in bypass of the containment structure and subsequent large offsite health consequences. As such, methods to assess the integrity of tubes during normal operations and to repair deficient tubes are an important element of the industry's safety programs and the staff's regulatory activities.

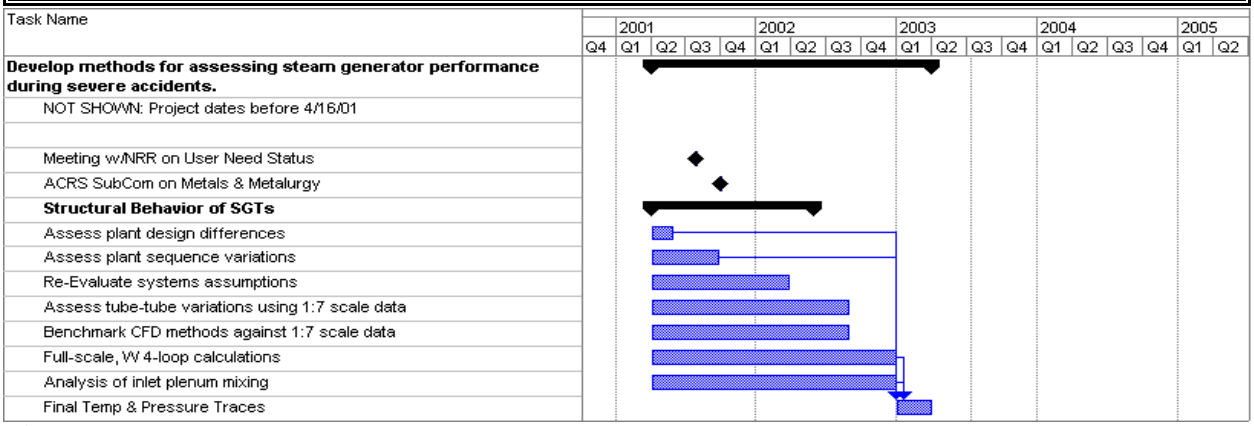
The staff currently is working to develop methods and tools to address steam generator tube integrity during postulated severe accidents in pressurized water reactors. The plan for the work includes three parts: probabilistic risk analysis, thermal hydraulics, and structural behavior of steam generator tubes and other reactor coolant system components. These analyses and their results are now being incorporated into a risk-informed framework to enable quantification of the frequency of containment bypass events from steam generator tube failures. The results from analyses related to tube failures have been completed and are now being incorporated into the risk-informed framework; results from analyses related to other materials that could fail before the SG tubes, thereby preventing tube failures and the resulting containment bypass (e.g., hot leg and surge line failures), will be incorporated into the risk-informed framework when they become available. Initially, the frequency of such failures resulting from postulated severe accidents will be determined, but this will be augmented later by consideration of steam generator tube ruptures resulting from non-severe accident initiators (e.g., main steamline breaks).

RES Priority: 11.8

Project Considerations: The timely completion of activities associated with this implementation activity requires close coordination, cooperation, and communication among numerous organizational units.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target**	**Revised**	**Completion**
Complete proposed framework for quantitative analysis of Severe Accident Induced-Steam Generator Tube Rupture (SAI-SGTR) risk	Apr. 1, 2002		Apr. 1, 2002
Complete DRAFT description of method to quantitatively determine SAI-SGTR risk	June 28, 2003		June 28, 2003
Develop improved methods for risk	TBD		
RCS components -- Phase II	September 2003		
Pilot application and refinement of SAI-SGTR risk analysis method	Feb., 2004		
Extend, generalize, and document SAI-SGTR risk analysis method	Sept. 30, 2004		
Expand risk analysis to include SG tube ruptures due to non-severe accident causes (e.g., steamline breaks)	TBD		
Final Reports	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



NOTE:

The above schedule shows completed work, or work nearing completion, related to thermal hydraulic and materials performance of SG tubes and other materials. Relevant results from those studies will be incorporated into a risk-informed framework to enable quantification of the containment bypass frequency due to tube failures during a SAI-SGTR (which will later be expanded to also include SG tube failures due to design basis accidents such as main steamline breaks).

A schedule for developing this risk-informed framework will be completed before the next update of this RI-RIP, and will be provided in that next update. That schedule will likely show further calculations in areas that were previously considered “completed,” as necessary to support calculation of the containment bypass frequency using the risk-informed method now under development

RS-EER1-1 Reactor Safety Arena

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

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

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

The evaluation of the current environment, the first phase of the program, was undertaken in the Fall 2001 and was designed to gain insight into internal NRC staff perceptions of risk-informed regulatory practices in the reactor program. The evaluation included individual interviews and focus groups conducted both at headquarters and with all four regions, and in total reached nearly 100 NRC employees nationwide. The evaluation found that the current environment within the reactor program is represented by the following general statements:

- NRC staff are demonstrating increasing acceptance of a risk-informed approach in the reactor program.
- Debate appears to have moved beyond whether risk insights should be integrated into activities, to discussion of how and when to implement risk-informed approaches.
- NRC staff and managers vary widely in their understanding of and experience with risk-informed approaches, as well as their acceptance of them. Staff ranged from being experts at conducting PRAs to self-describing a lack of familiarity with risk technology and applications.
- Barriers to implementation span a range of issues, including technical, organizational, communications issues, as well as levels of staff knowledge and experience.

The evaluation of the current environment has been documented in a report to senior agency managers in the reactor program (ADAMS accession No. ML022460161). The results of the evaluation and follow-up actions have been discussed with NRC staff in several division-wide employee meetings.

NRR Priority 10.0

Project Considerations: The second phase of the program includes the following pilot projects which are underway.

1. Publication of a monthly electronic newsletter, entitled, “Risk eBusiness”, on risk-informed activities. The newsletter is for NRC staff in the reactor program to keep them informed and up to date on what’s going on in the area of risk-informed regulation. Two editions have been published thus far. The newsletter is issued via e-mail to staff in NRR, RES, the Regional Offices, the ACRS and the Office of the EDO.

2. A Series of “Brown Bag” seminars began in July 2003. The purpose of the brown bag presentations is to provide an open forum for employees to discuss risk-informed activities within NRC in a more casual setting. The brown bags will provide opportunities for employees from different areas to learn about risk-informed topics, share information and expertise, and to express concerns and questions. The format of the sessions will emphasize interaction and discussion rather than lecture, and topics have been chosen based on recommendations from staff and managers as timely and of wide-spread interest.

3. In support of the NRR staff’s review of Risk-Management Technical Specification Initiative 4B a number of communication and training tools are being developed and implemented to help staff better understand the risk-informed approach to establishing allowed outage times being proposed by industry and to facilitate an objective review of the submittals that have been received from various industry groups.

In addition to the above, the staff is collecting information through focus group discussions and interviews regarding techniques and practices being used by various managers and supervisors in NRR to help their staff’s become more involved in risk-informed activities. This information will serve as the basis for developing guidance and recommended best practices.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Evaluate current environment for implementing risk-informed regulation in the reactor program, including current policies, practices, information base, methods and channels of communication, and staff and management perspectives.	December 2001	February 2002	February 2002
Complete pilot projects	October 2003		
Develop target environment	December 2003		
Assess Effectiveness of Changes	October 2004		

RS-EER1-2 Reactor Safety Arena

Implementation Activity: **Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees (RES & NRR)**

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The increased use of probabilistic risk assessments (PRA) in the regulatory decisionmaking process requires consistency in the quality, scope, methodology and data used in such analyses. These requirements apply to PRAs developed by industry to support specific, risk-informed licensing actions as well as to PRAs developed by NRC staff to analyze specific technical issues or to support Commission decisions. To this end, NRC worked with the American Society of Mechanical Engineers (ASME) to develop a national consensus standard setting forth specific guidance regarding the construction and execution of a PRA covering internal initiating events (excluding internal fire) at full power operation for a level 1 and limited level 2 (large early release frequency only) PRA. This standard, which was issued in April 2002, will help to ensure that PRAs developed in accordance with the standard are robust, consistent, and defensible and are documents from which regulatory decisions can confidently be made. In parallel, the staff also worked with the National Fire Protection Association (NFPA) to develop standards for fire risk analysis (See activity RS-MS8-6).

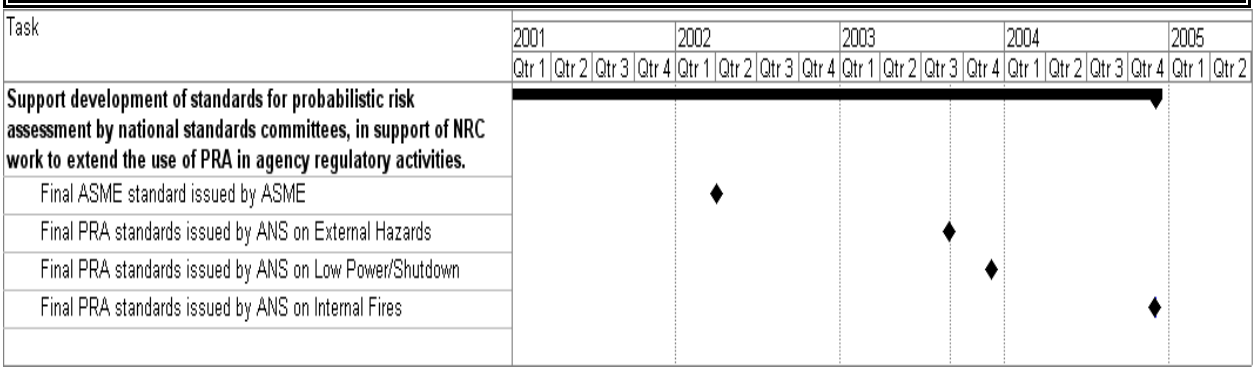
The NRC staff has been working with the American Nuclear Society (ANS) to develop a companion standard covering probabilistic analyses that would include the risk of internal fire, the impacts of external events on plant risk, and risk-significant events that could occur when a plant is operating at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

The NRC staff is continuing to work 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.

RES Priority: 10.5
NRR Priority: 6.0

Selected Major Milestones and Schedules			
Major Milestones[1]	**Original Target Date**	**Revised Date**	**Completion Date**
Final PRA standard issued by ASME	March 2001	March 2002	April 2002
Final PRA standards issued by ANS on External Hazards	June 2002	September 2003	
Final PRA standards issued by ANS on Low Power/Shutdown	June 2002	December 2003	
Final standard issued by ANS on Internal Fire	December 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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

RS-EER1-3 Reactor Safety Arena

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

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Decisions to pursue development of methods and models are made based on three general considerations: (1) the importance of new methods to risk-informing our regulations; (2) the adequacy of existing methods for understanding the risk implications of experimental findings and operational experience; and (3) the availability of methods for assessing the risk associated with the introduction of new technologies and new reactor designs. These criteria are associated with the issue of PRA model completeness and the degree to which PRA models adequately characterize risk-important failure modes and mechanisms. Thus, the more complete our understanding of plant risk, the more free are we to identify and remove unnecessary conservatism from our regulations and decisionmaking.

With these three considerations in mind, the following research efforts have been identified:

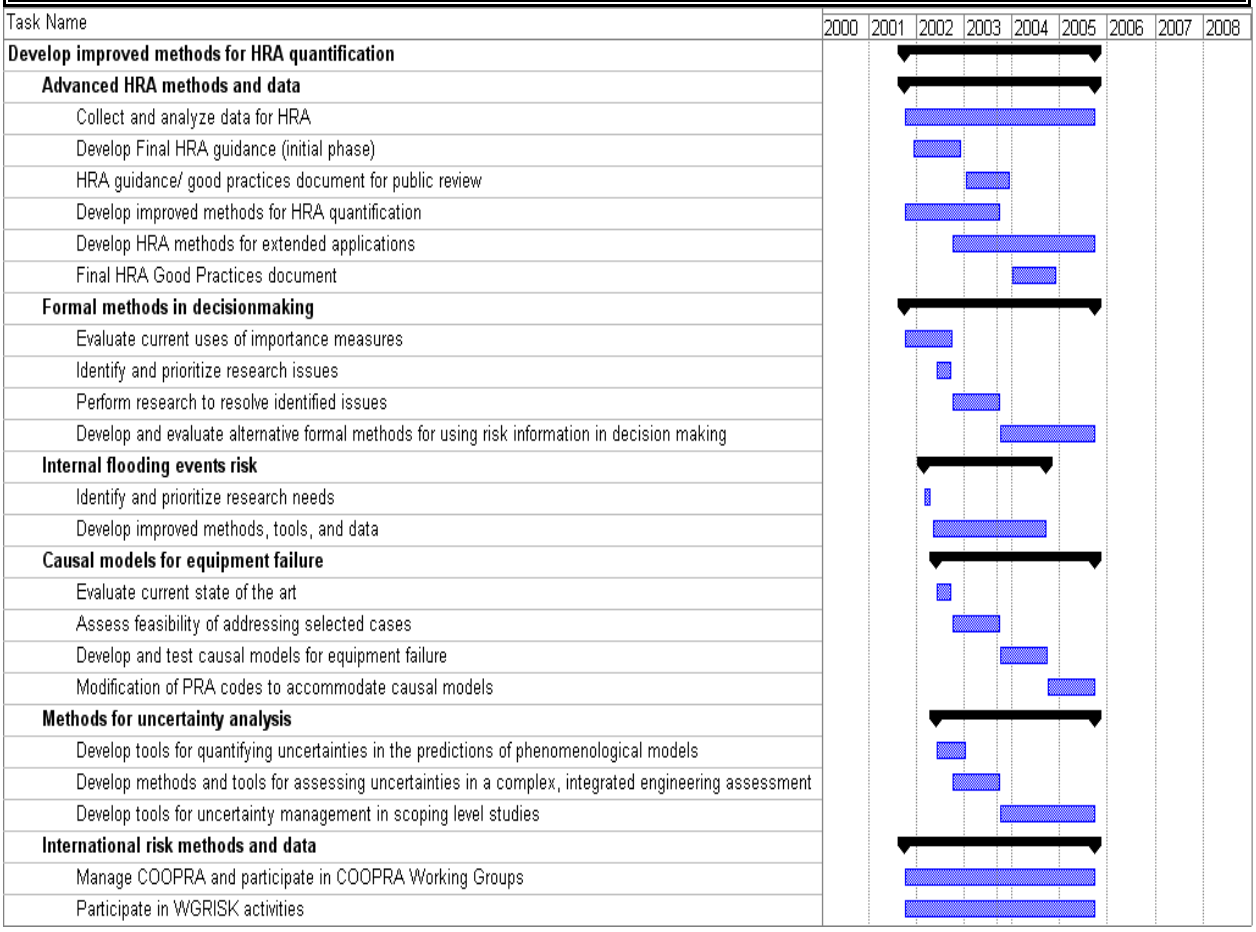
- Advanced human reliability analysis (HRA) data and methods
- Methods for Level 2 PRA
- Formal methods in decisionmaking
- Internal flooding events risk
- Causal models for equipment failure
- Methods for uncertainty analysis
- International risk methods and data

RES Priority: 10.5

Project Considerations: The quality of risk assessments is highly dependent upon the quality of the engineering analysis (e.g., thermal-hydraulic, severe accident, structural) that is used to calculate plant performance and success criteria. Although not included in this plan, work to improve and ensure the analytical tools used for these analyses are realistic and readily useable is vital to the success of risk-informed regulation.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete review and initial evaluation of potential HRA data sources	June 2002	December 2002	December 2002
Summarize insights from HRA R&D for HRA reviewers	September 2002		September 2002
Summarize issues associated with current uses of importance measures	September 2002		September 2002
Support international (CNSI and Halden) HRA activities on the identification of HRA data deeds.	September 2003		
Convene seventh international cooperative PRA research program meeting	September 2003		
Develop a prototype extraction tool allowing utilization of various HRA data sources.	December 2003		
Create HRA data repository	2004		
Complete development of HRA guidance / HRA “Good practices” document	December 2003		
Public review and revision of the HRA “Good practices” document - Final phase	September 2004		

Implementation Activity Gantt Charts Calendar Year



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RS-EER1-4 Reactor Safety Arena

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

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

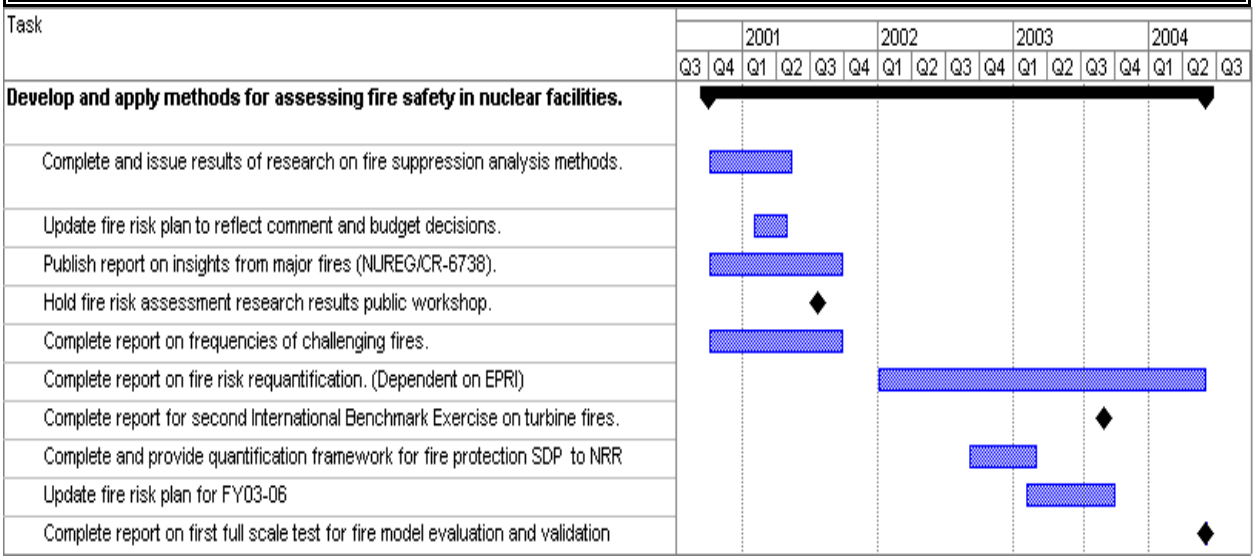
Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The development of performance-based fire standards and regulations requires a sound understanding of fire and its contribution to power plant risk. Current fire PRA models are not adequate to support credible, risk-informed changes to these standards and regulations. A fire risk program has been developed and is being implemented to address the complex issues associated with fire risk.

RES Priority: 10.0

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Provide quantification framework for fire protection SDP to NRR	March 2003		March 2003
Updated plan for fire risk	June 2003		June 2003
Complete report for second International Benchmark Exercise on turbine hall fires.	September 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-EER1-5 Reactor Safety Arena

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

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

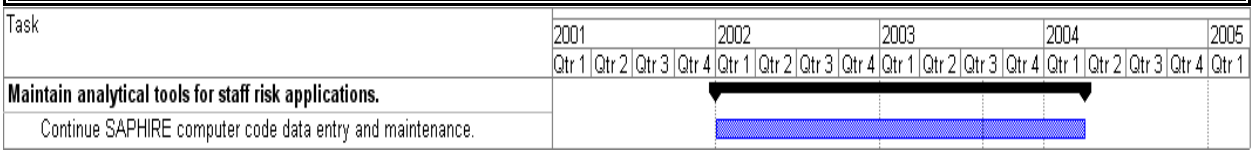
Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The NRC has developed and maintains the SAPHIRE (Systems Analysis Programs for Hands-on Analysis Integrated Reliability Evaluations) computer code for performing probabilistic risk analysis (PRAs). SAPHIRE offers state-of-the-art capability for assessing the risk associated with core damage frequency (Level 1 PRA) as well as 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 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, GEM.

RES Priority: 11.5

Project Considerations: The SAPHIRE code is needed to develop and evaluate PRA models. GEM provides a user-friendly interface which uses the SAPHIRE code. SAPHIRE/GEM is used widely in the NRC, and continues to evolve to meet the needs of the agency's risk-informed activities.

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-EER1-6 Reactor Safety Arena

Implementation Activity: **Assess regulatory effectiveness using risk information. (RES)**

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic*

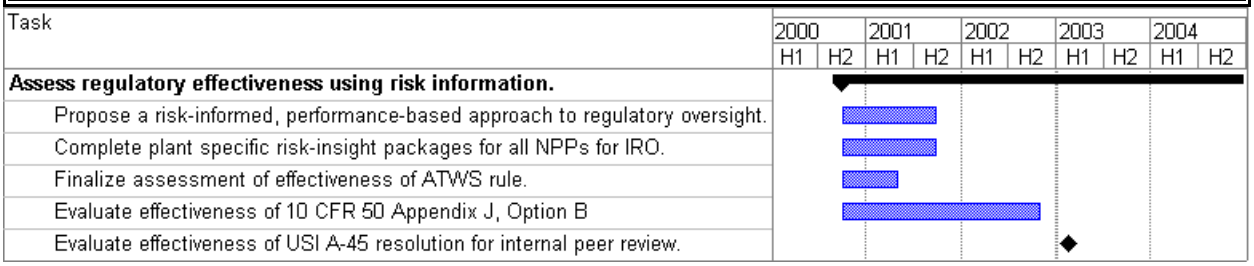
Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The staff will conduct an integrated evaluation of risk information, inspection findings, operating experience, domestic and international research results, and cost data to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

RES Priority: 8.5

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Evaluate effectiveness of ATWS rule	April 2001		April 2001
Evaluate effectiveness of USI A-45 resolution	September 2001	February 2003	August 2003
Evaluate effectiveness of 10CFR50, App J, Option B	January 2002	September 2002	November 2002

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



RS-EER1-7 Reactor Safety Arena

Implementation Activity: **Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.**

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The NRC is extensively using information from probabilistic risk assessments (PRAs) in its regulatory decisionmaking. To streamline staff review of licensee applications using risk insights, professional societies and the industry undertook the following initiatives to establish consensus standards and guidance on the use of PRA in regulatory decisionmaking:

- The American Society of Mechanical Engineers (ASME) has developed a standard for a Level 1 analyses (i.e., estimation of core damage frequency (CDF)) and a simplified Level 2 analysis (i.e., estimation of large early release (LERF)) covering internal events (transients, loss of coolant accidents, and internal flood) at full power.
- The Nuclear Energy Institute (NEI) has developed a "PSA Peer Review Guidance," (NEI-00-02) covering internal events at full power--Level 1 and simplified Level 2.
- The American Nuclear Society (ANS) is developing PRA standards for:
  - –external hazards with a tentative publication date of September 2003
  - –low power and shutdown with a tentative publication date of December 2003
  - –internal fires with a tentative publication date of December 2004

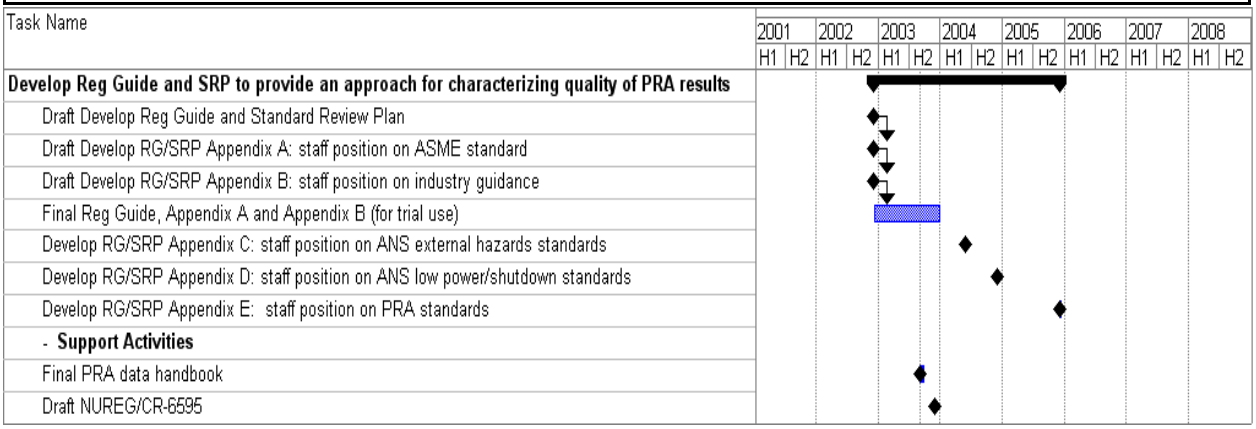
It is expected that licensees will use the PRA standards and industry guidance to help demonstrate and document the adequacy of their PRAs for a variety of risk-informed regulatory applications. Therefore, the staff should document its position on the adequacy of the standards and industry guidance to support regulatory applications. Such documentation will indicate in which areas staff review can be minimized and where additional review may be expected. To accomplish this, the staff will publish a new regulatory guide providing an approach for assessing the adequacy of PRA results used in support of regulatory applications and an accompanying Standard Review Plan (SRP) chapter.

The Regulatory Guide and associated SRP chapter are intended to support all risk-informed activities. The main body of the RG will: (1) summarize Attachment 1 of SECY-00-0162 and (2) provide advice on the use of PRA standards and industry guidance by licensees to determine the level of confidence that can be afforded PRA insights/results. The staff's position on each PRA standard and industry guidance will be provided in the appendices. To help support these efforts, the staff is also developing a data handbook for probabilistic risk assessments. The Data Handbook defines methods and tools for data analysis used in risk assessments. Additionally, the staff is revising NUREG/CR-6595, "An Approach for Estimating Frequencies of Various Containment Failure Modes and Bypass Events" to expand the approach for estimating large early release frequency (LERF) to include low power/shutdown conditions.

RES Priority: 10.5
NRR Priority: 6.0

Selected Major Milestones and Schedules			
Major Milestones[2]	**Original Target Date**	**Revised Date**	**Completion Date**
Draft of Reg Guide	December 2002		December 2002
Draft Appendix A: Staff position on the PRA standard issued by ASME on internal events	December 2002		December 2002
Draft Appendix B: Staff position on the PRA review guidance issued by NEI on internal events (NEI-00-02)	December 2002		December 2002
Appendix C: Staff position on PRA standards issued by ANS on External Hazards	December 2003	June 2004	
Appendix D: Staff position on standards issued by ANS on Low Power/Shutdown	December 2004		
Appendix E: Staff position on PRA standards issued by ANS on internal fire	December 2005		
Final Reg Guide for trial use	December 2003		
NUREG/CR-6595	March 2003	December 2003	
Final PRA Data Handbook	March 2003	September 2003	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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

RS-EER1-8 Reactor Safety Arena

Implementation Activity: Coherence Program for Reactor Safety Arena (NRR & RES)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Although a great deal of progress has been made towards risk-informing regulatory activities, the staff believes that some existing Reactor arena activities (regulations, staff programs and processes) may be inconsistent (or incoherent) with risk-informed practices. Many NRC regulations and processes have evolved in a less-than-integrated manner over the years. Consequently, the staff has been developing a program to address the coherence of regulatory activities. This program would provide an approach in which the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another. An inter-office working group has been formed and is developing a detailed action plan for the program to improve coherence among risk-informed activities. The staff intends to engage stakeholders throughout the process.

The objective of the coherence program is to develop and implement a plan such that "the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another." The program will be conducted in a phased approach.

In Phase 1, the staff is developing the criteria and process for achieving coherence in risk-informing reactor regulatory activities. Development of criteria includes the development of a unified safety concept. The unified safety concept is intended to enhance and strengthen existing processes for determining when reasonable assurance of adequate protection has been provided. Throughout this phase, the staff will maximize efforts to work from existing guidance documents; particularly the guidance for risk-informed changes to the technical requirements of 10 CFR Part 50.

In Phase 2, reactor regulations, staff programs, and staff processes will be evaluated to determine if they are consistent with the unified safety concept. Those found to be inconsistent will be identified as candidates for changes or refinements.

In Phase 3, staff effort required to refine the regulatory activity will be evaluated and then prioritized by its potential feasibility and desirability. The impact on security will be assessed during this phase also.

In Phase 4, the high-priority changes to the candidate regulatory activities will be selected and subsequently implemented. Implementation may result in reactor regulations, staff programs, or staff processes being refined.

NRR Priority: 9.0
RES Priority: 10.5

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Public Meeting on draft Process for a Risk-Informed Coherence Effort	March 2003		March 2003

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CHAPTER 2. NUCLEAR MATERIALS AND WASTE SAFETY ARENAS

Carl J. Paperiello, Arena Manager

2.1 Introduction

As directed by the Commission, the Office of Nuclear Materials Safety and Safeguards (NMSS) has been actively moving towards increasing the use of risk insights and information in its regulatory applications, where appropriate. NMSS is responsible for regulatory applications in the Nuclear Materials Safety and Nuclear Waste Safety arenas. Regulatory applications include, but are not limited to, rulemaking, guidance development, licensing and certification, and inspection activities for fuel cycle facilities, industrial and medical licensees, site decommissioning, transportation, and waste management and disposal.

Because of the varied nature of the activities in these two arenas, a single approach to "risk-informing" the NMSS regulatory applications, such as the probabilistic risk analyses (PRA) approach adopted by the Office of Nuclear Reactor Regulation, is not feasible. In the past, NMSS has used risk information in making regulatory decisions on a case-by-case basis. More recently, however, NMSS has developed a relatively comprehensive plan to risk-inform its regulatory applications, in consultation with the Commission. Currently, NMSS is implementing the plan.

The following sections briefly discuss the history behind the development and implementation of the NMSS plan for risk-informing its activities, as well as the plan itself and the current status of implementation. The discussion of the plan is followed by a detailed description of current risk-informed initiatives and activities.

2.2 Background

<u>DSI-12</u>

The Commission's Strategic Assessment and Rebaselining initiative included a direction-setting issue focused on risk-informed, performance-based regulation (DSI-12). In a staff requirements memorandum for COMSECY-96-061 (April 15, 1997) that addressed DSI-12, the Commission provided the following direction regarding the use of risk information in the Nuclear Materials and Waste Safety arenas:

> The staff should also reexamine the applicability of its risk-informed, performance-based or risk-informed less prescriptive approaches with regard to nuclear material licensees and to high level waste issues, to ensure that the needs of those licensees and those areas receive adequate consideration. The staff should perform a review of the basis for nuclear materials regulations and processes, and should identify and prioritize those areas that are either now, or could be made, amenable to risk-informed, performance-based or risk-informed less prescriptive approaches with minimal additional staff effort/resources. This assessment should eventually lead to the development of a framework for

applying PRA to nuclear material uses, similar to the one developed for reactor regulation (SECY-95-280), where appropriate.

SECY-98-138

NMSS staff provided an initial response to the Commission in SECY-98-138 (June 11, 1998), informing the Commission that it reviewed the framework for applying PRA to reactor regulation and evaluated the applicability of the reactor framework to nuclear materials and waste applications. The staff determined that, while the reactor framework and a materials and waste framework would be similar in purpose and principles, a materials and waste framework would likely differ from the reactor framework in some of its specifics. The staff provided a detailed discussion of assumptions that would underlie, and elements that would be incorporated into, a materials and waste framework and provided a schedule for developing the framework.

In SECY-98-138, the staff also identified several gaps in the foundation of pertinent experience and policy necessary to develop and apply a framework to material and waste applications:

- limited experience with strengths and limitations of potentially useful analytical methods;
- limited knowledge of which of these methods may be applied usefully to a specific nuclear materials useage;
- lack of established policy (similar to the reactor safety goal policy statement); and
- insufficient staff training programs.

The staff indicated that gaps in experience and knowledge would be addressed through ongoing risk-informed initiatives and activities that would test or develop system analysis methods for certain nuclear material and waste applications. The staff proposed to address policy gaps by recommending to the Commission (1) whether materials and waste risk guidelines should be developed, and (2) criteria for determining whether risk-informing a given materials or waste regulatory application is appropriate. Finally, the staff proposed to identify training necessary to implement the framework and to develop an appropriate training program.

SECY-99-100

NMSS staff completed its response to the Commission through SECY-99-100 (March 31, 1999), building on the information and proposals provided to the Commission in SECY-98-138. In SECY-99-100, the staff proposed a four-part framework for using risk assessment in nuclear materials waste regulation:

Part 1 - Define regulatory application areas in which risk assessment methods can play a role in NRC's decision-making process. Group the areas by regulated use (e.g., fuel fabrication) and within each use by regulatory application (e.g., graded quality assurance).

Part 2 - Evaluate the current considerations underlying the application area to ensure that the existing approach is altered only after careful consideration. Factors to be considered include deterministic considerations (hazard, relative

importance of human vs. equipment error, defense-in-depth, codes and standards); current risk considerations (e.g., use of performance assessment in geologic repository licensing); and institutional considerations (existing statutory requirements, Agreement State issues, and licensee circumstances).

Part 3 - Evaluate new risk considerations in support of the proposed regulatory action. Elements of this evaluation include scope and level of detail of the risk assessment, sensitivity and uncertainty analyses, and assurance of technical quality.

Part 4 - Integrate the current considerations and new risk considerations to ensure a consistent and scrutable decision-making process and to ensure that the underlying bases for rules, regulations, regulatory guides, and staff review guidance are maintained or modified to the extent supported by the conclusions of Parts 2 and 3.

The staff proposed a five-step process to implement the framework:

Step 1 - Identify candidate regulatory applications that are amenable to expanded use of risk assessment information (i.e., risk-informed approaches) and identify the responsible organizations.

Step 2 - Decide how to modify the current approach of the regulatory application areas that are determined to be amenable to risk-informed approaches.

Step 3 - Change regulatory approaches.

Step 4 - Staff training for implementing risk-informed approaches.

Step 5 - Develop or adapt risk-informed tools.

The staff proposed to accomplish the first step of the framework implementation process by identifying a full set of regulatory application areas and then screening them to establish a set of applications that would be amenable to risk-informed regulatory approaches. Because of limited resources, the staff proposed a step-by-step approach based on prioritization, rather than a comprehensive reevaluation in all areas simultaneously. Based on the screening, the staff would decide whether it seemed appropriate to change the existing regulatory framework and, if so, would propose risk metrics and goals as a basis for interactions with stakeholders. The interactions would include stakeholder workshops, Internet postings, and possibly pilot projects.

To accomplish the second step of the framework implementation process, the staff proposed to use stakeholder workshops, Internet postings, and pilot projects as important sources of information to address the following considerations: (1) how is the staff expected to use risk insights and risk assessment in developing regulations and guidance, licensing, inspection, assessment, and enforcement? and (2) how is the licensee expected to use risk insights and risk assessment in planning and conducting its operations?

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The third step of the framework implementation process proposed by the staff was to make the appropriate changes to the regulatory approaches, for example, by modifying rules and regulations, staff review plans, and regulatory guides. The fourth step of the proposed framework implementation process was staff training to assure consistent and knowledgeable implementation of the new risk-informed approaches, and the fifth step was to develop or adapt needed tools (e.g., risk assessment methods or computer codes).

In addition to the four-part framework for using risk assessment in nuclear materials and waste regulation, and the five-step process for implementing the framework, NMSS staff also proposed to develop risk metrics and goals to address risk management issues in regulating nuclear material uses and radioactive waste management and to support risk-informed policies and decisionmaking. Finally, SECY-99-100 proposed the formation of a joint Advisory Committee on Reactor Safeguards (ACRS)/Advisory Committee on Nuclear Waste (ACNW) subcommittee to provide technical peer review of the staff's future efforts.

SRM for SECY-99-100

On June 28, 1999, the Commission issued its staff requirements memorandum (SRM) for SECY-99-100. The Commission approved (1) the staff's proposal to implement a framework for using risk assessment in regulating nuclear material uses and disposal; (2) the staff's proposal for addressing risk management issues, including the development of risk metrics and goals; and (3) the formation of a joint ACRS/ACNW subcommittee to peer-review the staff's efforts in this area. Also, the Commission approved the reallocation of six staff full-time equivalents (FTEs) to proceed with this effort.

The Commission indicated that staff should develop appropriate material risk guidelines, analogous to the NRC reactor safety goals, to guide the NRC and to define what "safety" means for the materials program. The Commission directed the staff to develop these goals through an enhanced participatory process, including broad stakeholder participation. Also, in developing a standard or standards for risk-informed regulation in NMSS, the Commission indicated that the staff should give due consideration to existing radiation protection standards in Part 20, and that the standards should allow for equivalent levels of reasonable assurance of adequate protection across the spectrum of regulated materials activities and should be consistent with risk-informed practices being applied to nuclear power plant regulation.

2.3 NMSS Plan for Risk-informing Materials and Waste Safety Arenas

NMSS is following a three-phase plan to implement the framework described in SECY-99-100. The first two phases address the first step in the framework implementation process described in SECY-99-100 (identified above). The first phase focuses on developing a systematic approach for identifying candidate NMSS regulatory applications that may be amenable to increased use of risk information. The second phase focuses on applying the systematic approach developed through the first phase to identify the candidate NMSS regulatory applications. Finally, the third phase addresses Steps 2 through 5 of the SECY-99-100 framework implementation process. The third phase focuses on the actual modification of the

identified regulatory applications to make them more risk-informed. The three phases are shown in Figure 2-1. Each of these three phases is discussed below.

2.3.1 Phase 1

Phase 1 represents NMSS's initial implementation of the three Commission directives identified in the SRM for SECY-99-100 and described above in Section 2.2.

In August 1999, NMSS staff were identified and reassigned to form the NMSS Risk Task Group. The Risk Task Group currently reports to the director of NMSS, reflecting the priority the director places on increasing the use of risk information in the regulatory applications of NMSS. Also, the director formed the NMSS Risk Steering Committee, composed of management at the division and office level . The NMSS Risk Steering Committee provides management and policy direction to the Risk Task Group as necessary.

Screening Criteria

One of the first efforts of the Risk Task Group was the formulation of draft screening criteria for identifying NMSS regulatory applications amenable to increased use of risk information. As part of the effort to use an enhanced public participatory process in developing the framework, the Risk Task Group held a public workshop in Washington, DC, on April 25 and 26, 2000. The Risk Task Group published draft screening criteria in a *Federal Register* notice (65 FR 54323, March 16, 2000) announcing the workshop. The purpose of the workshop was to (1) solicit public comment on the draft screening criteria and their applications, and (2) solicit public input for the process of developing risk guidelines for nuclear materials and waste applications. The workshop included participation by representatives from NRC, the Environmental Protection Agency, the Department of Energy, the Occupational Safety and Health Administration, the Organization of Agreement States, the Health Physics Society, the Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. The consensus of the workshop participants was that a case study approach and iterative investigations would be useful for the following purposes: (1) to test the screening criteria, (2) to show how the application of risk information has affected or could affect a particular area of the regulatory process, and (3) to develop risk guideline parameters and a first draft of risk guidelines for each area. These are similar to the gaps in the NMSS foundation that should be addressed to support risk-informing regulatory applications, as identified by staff in SECY-98-138.

Based on feedback received from stakeholders, the Risk Task Group, in consultation with the Risk Steering Committee, finalized the draft set of screening criteria for identifying NMSS regulatory applications amenable to increased use of risk information. The draft criteria consisted of four criteria which addressed whether a benefit would be realized from modifying a regulatory approach, based on risk information. The four "benefit criteria" reflected the four performance goals identified in the NRC strategic plan: maintaining safety; protecting the environment and the common defense and security; increasing public confidence; making NRC activities and decisions more effective, efficient, and realistic; and reducing unnecessary regulatory burden on stakeholders. The remaining three criteria addressed technical feasibility,

implementation costs, and other factors that could negate the potential benefits of, or significantly hinder, modifying the regulatory approach.

Case Studies

Also based on the April 2000 public workshop, the Risk Task Group developed a plan for conducting a series of eight case studies (1) to test the usefulness and applicability of the draft screening criteria, (2) to evaluate how the application of risk information has affected or could affect particular areas of the NMSS regulatory process, and (3) to draft risk metrics and goals (i.e., risk guidelines) that may be used to address risk management issues in the NMSS Materials and Waste Safety arenas. A draft of the case study plan was issued for public comment (65 FR 54323), a public workshop was held in September 2000, and the final case study plan was released in October 2000 (65 FR 66782).

The Risk Task Group began the case studies in November 2000. The following case study areas were selected to reflect the diversity of NMSS materials and waste regulatory applications: regulation of generally licensed and specifically licensed devices (gas chromatographs, fixed gauges and static eliminators), decommissioning of the Trojan reactor site under the 10 CFR Part 20 license termination rule, transportation of the Trojan reactor vessel, regulation of uranium recovery facilities, certification of the Paducah gaseous diffusion plant, and licensing of the Idaho National Engineering and Environmental Laboratory independent spent fuel storage installation.

The case studies were completed and a final report was distributed in December 2001 to the NMSS Risk Steering Committee “Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments”, December 2001, addenda February 2002, ADAMS ML013610470. The Risk Task Group met with the NMSS Risk Steering Committee in January 2002 and discussed the following conclusions:

- A well-defined procedure for identifying candidate applications in NMSS for risk-informing was successfully tested and was finalized as a set of screening considerations. Overall, the case studies demonstrated that the screening considerations contained all the relevant elements needed for risk-informing and could be a useful decisionmaking tool. However, the application could be subjective, so guidance is needed. The experience of carrying out the case studies also indicated that since the draft “screening criteria” do not have just yes/no answers, they should be more properly identified as screening considerations, that is, a set of factors that need to be considered in risk-informing.

- The case studies collectively illustrated that risk information has been used for some time in making regulatory decisions. The case studies were effective in indicating where decisions or processes are consistent with the agency’s strategic goals. Furthermore, they helped to highlight some of the areas in which there are shortcomings in the regulations or regulatory process.

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- The studies also showed that risk guidelines are feasible and decision-making and risk management can be facilitated if a clear set of risk guidelines exists. A preliminary set of risk guidelines was developed and needs to be tested and refined. Risks to the workers were found to be significant in comparison to public risks. For some facilities, chemical risks were found to be comparable to or greater than the radiological risks.

- Information, tools, methods, and guidance needs were identified and the necessary tools could be assembled to make the risk-informing process more effective in NMSS. There has been a fairly significant application of risk methods and applications in some areas and somewhat less experience in other areas. One of the major gaps in the methods is the identification and development of a robust and simple method for incorporating human factors and estimating human reliability in the very wide range of situations encountered and activities performed by NMSS licensees.

Specific Risk-Informed Activities

The primary Phase I activity described in the preceding paragraphs focused on the development of the general approach to systematically incorporate risk information into NMSS regulatory applications and support risk management decisionmaking. Concurrent with this activity, NMSS has been incorporating risk insights and information into specific regulatory applications. These applications were identified through several mechanisms, including operating experience, Commission direction, stakeholder suggestion, and staff initiatives. Where appropriate, NMSS staff responsible for these initial “risk-informed” applications interacted with Risk Task Group staff who are involved in the case studies and the development of the screening criteria and risk metrics and goals.

NMSS Risk Training

Also during Phase I, NMSS began to develop a training program addressing the use of risk information in materials and waste regulatory applications. The need for this training program was identified in SECY-98-138. NMSS developed a three-tier program, reflecting the depth and complexity of the course content. The Tier I and Tier II courses provide training on the general relevance of risk information and risk assessment methods in the Materials and Waste arenas to management and administrative and technical staff. Tier III courses provide training on specific aspects of risk assessment, management, and communication. Tier III training needs are identified through interaction with the NMSS division-level management. NMSS developed and began to offer the Tier I and Tier II courses during 2000. NMSS began to develop and offer some of the initial Tier III courses during 2001.

Phase I concluded in December 2001 with the completion of the case study activity, the finalization of the screening considerations for identifying regulatory applications, and the development of draft risk metrics and goals.

2.3.2 Phase 2

Phase 2 began in January 2002. The second phase of the NMSS plan to risk-inform its regulatory applications focused on applying a systematic approach to identify NMSS regulatory applications amenable to being risk-informed. This identification of activities will serve as the NMSS road map towards comprehensively risk-informing its regulatory activities. The second phase consisted of a systematic and comprehensive review of NMSS regulatory applications to identify (1) the risk-informed activities that have been completed, (2) the risk-informed activities that are currently ongoing, and (3) potential future risk-informed activities that may be pursued. NMSS regulatory applications that may be risk-informed include, but are not limited to, rulemaking, guidance development, licensing and certification, and inspection activities for fuel cycle facilities, industrial and medical licensees, site decommissioning, transportation, spent fuel storage, and waste management and disposal.

The Phase 2 effort was completed and a final report was distributed in April 2002 to the NMSS Risk Steering Committee "Risk-Informing the Materials and Waste Arenas*:* Phase 2 Report", April 2002, ADAMS Package ML021020317. The NMSS Risk Steering Committee was briefed on the Phase 2 effort in June 2002.

Separately, but in parallel with Phase 2, the RES and NMSS staff continued to develop and refine risk guidelines for the Materials and Waste Safety arenas in accordance with an NMSS user-need memorandum. The case studies conducted under Phase 1 demonstrated that risk guidelines and qualitative measures of what is safe enough could be useful or may be necessary in risk-informing specific activities in the Materials and Waste arenas.

2.3.3 Phase 3

Phase 3 involves the actual modification of the regulatory applications through the implementation of risk-informed activities. In the five-step implementation process described in Section 2.1.1 of SECY-99-100, Phase 3 corresponds to Steps 2 through 5.

NMSS has been actively conducting risk-informed activities on a case-by-case basis, prior to and concurrent with the Phase 1 through 3 activities. Phase 2 compiled the completed and ongoing activities with potential future activities. Phase 3 continues with the implementation of these activities, as prioritized through the planning, budgeting, and performance management (PBPM) process, discussed in the following section.

2.3.4 Prioritization of Materials and Waste Safety RIRIP Implementation Activities

In accordance with 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. Although a common prioritization scheme is currently being developed, the prioritization processes followed by NMSS, NRR, and RES management are not the same. However, all three offices use the agency's strategic plan performance goals to prioritize office activities as part of the budget process. NMSS indicates its priorities by ascribing to each activity a low, medium, or high priority. Staff activities are prioritized as they relate to maintaining safety;

improving effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence.

As with other staff activities, changes in priorities of the staff's risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities.

2.4. Description of Current Initiatives and Activities

Current initiatives and activities to risk-inform the regulatory applications of the Materials and Waste Safety arenas include the following:

Nuclear Material Safety Arena

MS-EER1-1	Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process
MS-EER1-2	Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities
MS-EER1-4	Develop Risk Guidelines for the Materials and Waste Arenas
MS-EER1-5	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
MS-EER1-6	Risk-Informed Decisionmaking Guidance Development
MS-EER1-7	Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications
MS-EER2-1	Multi-phase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations)
MS-MS1-3	Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements
MS-MS2-1	Materials Licensing Guidance Consolidation and Revision
MS-MS2-3	Implementation of Part 70 Revision
MS-RB1-1	Revise Part 36: Panoramic Irradiators (PRM-36-01)
MS-RB1-2	Revise Part 34: Radiography (PRM-34-05)

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Nuclear Waste Safety Arena

WS-MS1-1	Probabilistic Risk Assessment of Dry Cask Storage Systems
WS-MS1-2	Incorporate Risk Information into the Decommissioning Regulatory Framework
WS-MS1-3	Incorporate Risk Information into the High-Level Waste Regulatory Framework
WS-MS1-4	Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs

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

Figure 2-1. Three-Phase Plan for Risk-Informing the Materials and Waste Safety Arenas

Phase 1

- Develop draft screening criteria for identifying materials and waste activities amenable to increased use of risk information
- Conduct Materials and Waste arena case studies to test draft criteria and identify risk guidelines
- Finalize screening criteria
- Develop draft risk metrics and goals (risk guidelines)
- Continue with specific ongoing risk-informed initiatives and activities
- Develop risk training program for NMSS management and staff

Phase 2

- Systematically review materials and waste regulatory applications and apply screening criteria
- Identify regulatory applications amenable to being risk-informed
- Categorize and prioritize
- Define scope, resources, schedule for near-term activities

Phase 3

Ongoing implementation of specific risk-informed initiatives and activities

MS-EER1-1 Materials Safety Arena

Implementation Activity: Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

In the SRM for SECY-99-100, dated June 28, 1999, the Commission approved the staff's proposed framework for risk-informed regulation in NMSS. The NMSS Risk Task Group (RTG) has been implementing this framework in three phases. Phase 1 established a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information. RTG conducted eight case studies of NMSS activities to evaluate how risk information has been used or could be used to improve NMSS regulatory processes, including numerous stakeholder meetings, interviews, and site visits. Case study results were integrated with other related risk assessments and were documented in *Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments* (December 2001; addenda February 2002). Through Phase 1, RTG was able to:

- Develop screening considerations for identifying regulatory applications that may be amenable to being risk-informed, and develop a guide for how to use the screening considerations (*Risk-Informing the Materials and Waste Arenas: Guidance for Applying the Screening Considerations*, January 2002, ML020300067)
- Establish the feasibility of developing risk guidelines for the nuclear material and waste arenas, and form a framework for continued development of risk guidelines
- Evaluate the value of using risk insights and information in the nuclear material and waste arenas
- Identify tools, data and guidance necessary to risk-inform NMSS activities

In Phase 2, RTG applied the systematic approach developed in Phase 1 to identify NMSS regulatory applications amenable to being risk-informed. Phase 2 identified potential future risk-informed activities within the scope of each division, as well as activities that cut across divisions. This effort identified areas where organizational effectiveness and efficiencies could be realized with the use of risk information. Phase 2 was initiated in January 2002 and completed in April 2002. Results are documented in *Risk-Informing the Materials and Waste Arenas: Phase 2 Report* (April 30, 2002, ML021210081). RTG met with the NMSS Risk Steering Committee to discuss the results and receive further guidance on implementing the activities identified in Phase 2 in June 2002.

Phase 3 involves the ongoing implementation of risk-informed initiatives and activities, including those identified in Phase 2. Phase 2 crosscutting activities now in progress (described in subsequent pages) include:

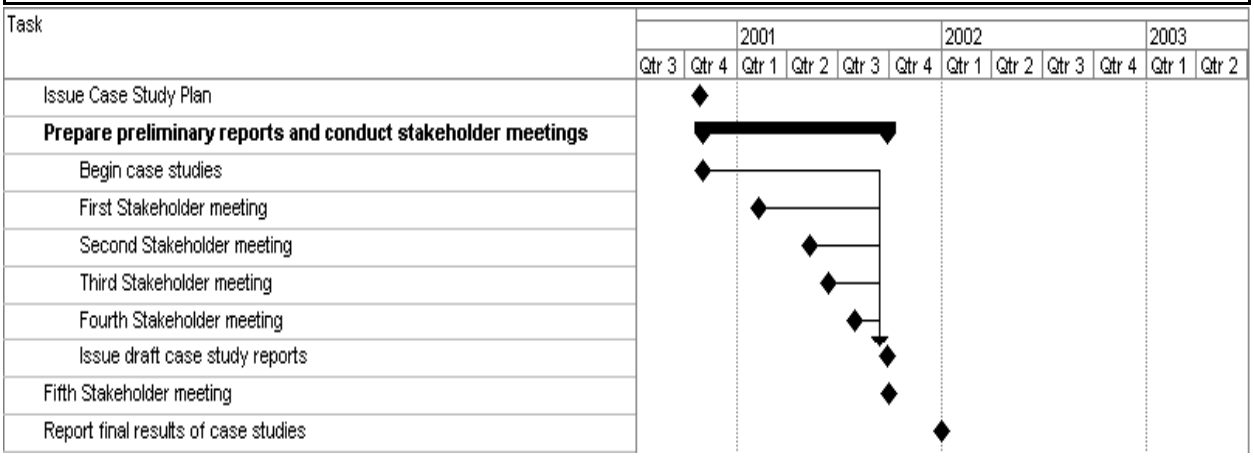
- development of a guide for performing a risk analysis (completed)
- development of risk guidelines (joint effort with RES)
- assessment of the relative safety/risks associated with spent fuel (completed)
- development of a guide for risk-informed decision
- initiation of additional training courses for the NMSS staff to advance the use of risk information
- publication of a risk-informed and performance-based rule for disposal of high-level radioactive waste at Yucca Mountain (completed)

NMSS Priority: Medium

Project Considerations: The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts. Additionally, the case-study approach involved numerous public workshops to solicit stakeholder input, in an enhanced participatory process. This activity is inter-related with other agency efforts. RTG is coordinating with other NMSS staff when an ongoing regulatory activity relates to this activity. Also, in FY02 RES and RTG initiated a joint effort to continue development of risk guidelines and other tools, guidance, and data that may be need to risk-inform materials and waste regulatory processes and this collaboration continues through FY03.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue case study plan			October 2000
Complete preliminary reports and initial stakeholder meetings			July 2001
Complete final case study reports and consolidated stakeholder meeting	December 2001		October 2001
Report final results of case studies (complete Phase 1)	March 2002		December 2001
Complete guidance for using screening considerations			February 2002
Complete identification of activities (Phase 2)			April 2002
Meet with NMSS Risk Steering Committee for further guidance	June 2002		June 2002
Implement risk-informed activities (Phase 3)	to be determined on case-by-case basis		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-EER1-2 Materials Safety Arena

Implementation Activity: Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategies: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

The NMSS Risk Task Group staff has worked with the NRC Technical Training Center (TTC) to develop a series of courses to train NMSS staff on risk activities in the Materials and Waste arenas. The following Tier I, II, and III risk assessment courses are now offered through the NRC's Professional Development Center:

- P-400 Introduction to Risk Assessment in NMSS
- P-401 Introduction to Risk Assessment in NMSS for Technical Managers
- P-402 Introduction to Risk Assessment in NMSS for Administrative Staff
- P-403 Quantitative Risk Assessment
- P-404 Hazards Analysis for DOE SARs and QRAs, Including Integrated Safety Analysis (ISA)

RTG has developed a Tier III course on the use of NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (P-405). The course provides a general understanding of the process of developing risk analysis to populate the underlying database of NUREG/CR-6642. Examples are presented of possible uses of the information in regulatory decisionmaking and provide an overview of the risk analysis methodology, methods to define systems, uncertainty in human performance assessment, and basic use of the Byproduct Material System Risk database. The pilot for this course was held in July 2002. Six instructor-led session (two in HQ and one in each Region) were conducted. The course will continue to be available for self study on CD-ROM.

RTG is working with the Technical Training Center (TTC) and the Idaho National Engineering and Environmental Laboratory (INEEL) to develop an NMSS Human Reliability Assessment (HRA) course (P-406). The intent of this tier III course is to improve NMSS staff's understanding of the various HRA methodologies, their strengths and weaknesses, and how they can be used to assess the impact to the total risk due to human errors for materials and waste applications. Representatives from all divisions and Region I attended the pilot course on March 17 - 19, 2003. Feedback will be factored into the course material before the course is officially offered to the NMSS staff in FY 2004.

RTG is currently re-evaluating the existing risk training program. It has become apparent that we need to minimize duplication between the various existing courses, update the course material and design new course. RTG is working on training that would provide description of Commission policy on risk-informing, NMSS' risk-informing initiative, application of risk insights, and the guidance documents that are available and being developed.

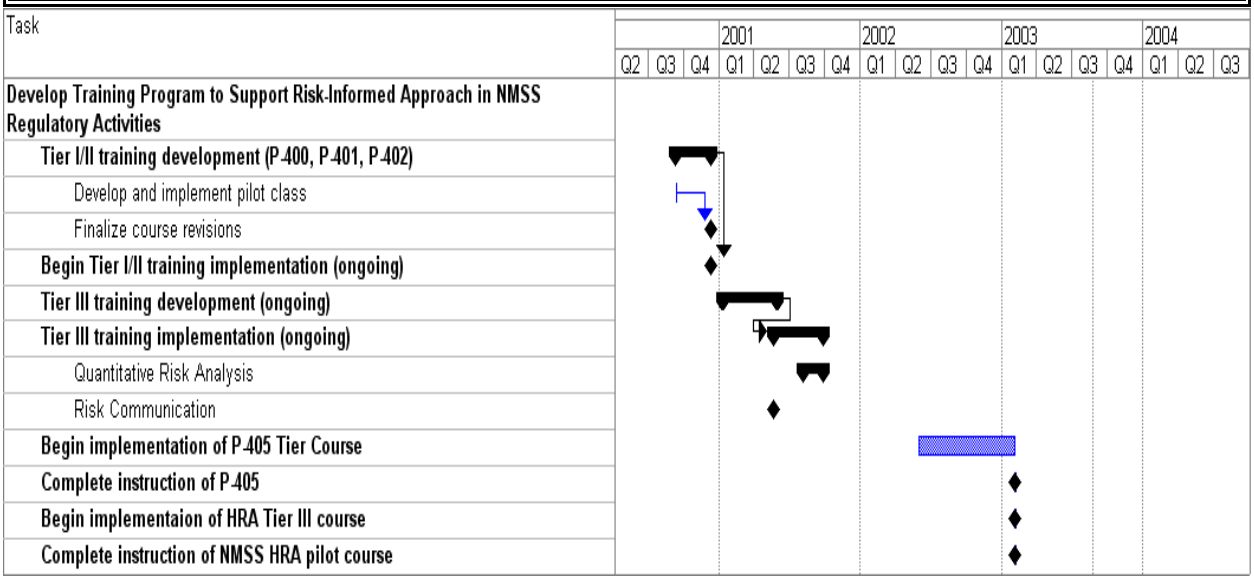
NMSS Priority: Medium

Project Considerations: Evaluation of Tier III training program for risk specialists is ongoing. The staff is working with the TTC to develop the NMSS risk training materials. In developing the Tier III training, all NMSS divisions were consulted to determine needs. Tier III training courses will support the divisions' activities where a need was identified. Staff will also work with external training providers to bring into the Agency existing training courses, where appropriate.

NMSS has developed a communication plan on risk-informing materials and waste regulations . The plan addresses communication with internal stakeholders and the development of the NMSS risk training program.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Begin implementation of P-405 Tier III course	June 2002	July 2002	July 2002
Complete instruction of P-405	February 2003		February 2003
Begin implementation of HRA Tier III course	March 2003		March 2003
Begin implementation of one-day Introductory Risk course	March 2003		March 2003
Offer P-406 regular HRA course	2nd half FY04		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-EER1-4 Materials Safety Arena

Implementation Activity: Develop Risk Guidelines for the Materials and Waste Arenas

(Lead Organization: NMSS/RTG and RES)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

In Phase 1, the NMSS Risk Task Group worked with Brookhaven National Laboratory to begin the process of developing risk guidelines for the Materials and Waste arenas. As a result of the case studies, the feasibility of risk guidelines for the Materials and Waste arenas was established and a first draft of risk guidelines was developed. The case studies also yielded the following key insights with regard to risk guidelines:

- Risk Guidelines and qualitative measures of what is safe enough could be useful in risk-informing specific situations within the Materials and Waste arenas.
- There are no fundamental impediments to the expansion and broader application of risk information across the spectrum of NMSS-regulated activities.
- Risk information can be valuable as an additional input to risk management decisions that NMSS must make.
- Risk information can help make the existing regulatory framework more rational.
- An integrated and balanced risk management program would recognize both public and worker risks as well as radiological and non-radiological risks at regulated facilities.

The Risk Task Group initiated a joint effort with RES to continue developing materials and waste risk guidelines and risk metrics, and to develop other tools, methods, data, guidance and standards necessary for implementing risk-informed approaches in NMSS. A User Need Memo was sent to RES on January 30, 2002. In response to the User Need, RES has initiated a contract with Brookhaven National Laboratory to continue to support risk-informed initiatives for nuclear materials and waste. During FY 2003, BNL submitted a progress report on risk guideline development and briefed the PRA Steering Committee.

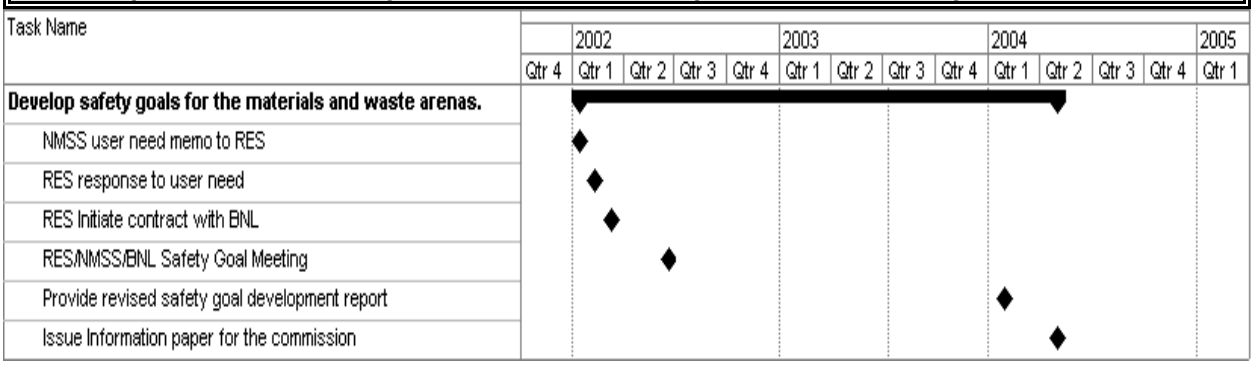
Furthermore, NMSS is developing a guidance document on the risk-informed decisionmaking (RIDM) process for materials and waste applications (see MS-EER1-6). Risk guidelines would be a vital input to such a decisionmaking process. Revision 0 of the guidance document will be completed by the end of calendar year 2003. This revision will explain how risk guidelines or quantitative risk guidelines can be used in NMSS, through several pilot studies.

NMSS Priority: Medium

Project Considerations: Risk guideline development is one of the crosscutting activities identified in Phase 2. The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts. In accordance with the SRM to SECY-99-100, risk guidelines will be developed through an enhanced participatory process. However, before public input is sought, RTG will conduct pilot studies to test the risk-informed decisionmaking guidance, to get a better understanding of how any proposed risk guidelines or guidelines fit into the overall risk-informed decisionmaking process.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
NMSS user need memo to RES			January 2002
RES response to user need			February 2002
RES Initiate contract with BNL			March 2002
RES/NMSS/BNL Risk Guideline Meeting	June 2002		June 2002
Provide revised draft risk guideline development report	February 2003	April 2003	April 2003
Next revision to risk guideline report	February 2004		
Issue paper for the Commission	Spring 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-EER1-5 Materials Safety Arena

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**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient and realistic (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.*

The Part 40 Jurisdictional Working Group (Working Group) includes a representative from various Federal agencies and a representative from the States (representing the Organization of Agreement States and the Conference of Radiation Control Program Directors). The Working Group evaluated current jurisdictional authorities for the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium or thorium. The Working Group has found that most materials/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 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. As such, 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 their review.

NMSS Priority: High

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Recommendations from the Part 40 Jurisdictional Working Group to the Commission	June 2002	March 2003	May 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

Task Name	2003												2004	
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Evaluation of regulation of low-level source material containing less than 0.05 percent U and/or Th.														
Recommendations from the Part 40 Jurisdictional Working Group to the Commission					♦									

MS-EER1-6 Materials Safety Arena

Implementation Activity: Risk-Informed Decisionmaking Guidance Development

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

RTG, with support from the Brookhaven National Laboratory, is currently developing a guidance document on the Risk-Informed Decisionmaking (RIDM) process. The objective of this RIDM guidance document is to facilitate consistent and systematic use of risk insights in making regulatory decisions. RTG is planning to conduct pilot studies to support the divisions in their risk-informing efforts and test the guidance document to assure that the proposed decisionmaking algorithms are appropriate for NMSS applications.

IMNS Pilot Study

The subject of this pilot study relates to regulatory requirements associated with the control and accountability of chemical agent detectors owned by the U.S. Armed Services. The large number of detectors (approximately 60,000) combined with the potential for continuing frequent loss of these devices (19 detectors have been lost within a year and a half) requires significant regulatory resources which may not be commensurate with the significance in health risks resulted from the loss of these detectors. This situation appears to represent an opportunity for NMSS to be more effective and efficient and to reduce unnecessary regulatory burden while maintaining safety. Using the draft guidance document and the risk information contained in NUREG/CR-6642, RTG and IMNS plan to generically address the risk significance of these devices and propose some form of regulatory burden reduction, such as the use of enforcement discretion, Enforcement Policy changes, or rulemaking changes, or through a combination of all three methods. This pilot study is currently underway. It is anticipated that the pilot study will be completed by the end of FY 2003.

SFPO Pilot Study

RTG and SFPO initiated the storage pilot study on July 9, 2003. The purpose of the storage pilot study is to (1) test the effectiveness of the NMSS risk-informed decision-making (RIDM) process and draft guidance guidance and (2) identify risk insights that could enhance specific aspects of licensing reviews for spent fuel storage in dry casks. It is anticipated that the pilot study will be completed by the end of 2003.

Retrospective Pilot Study

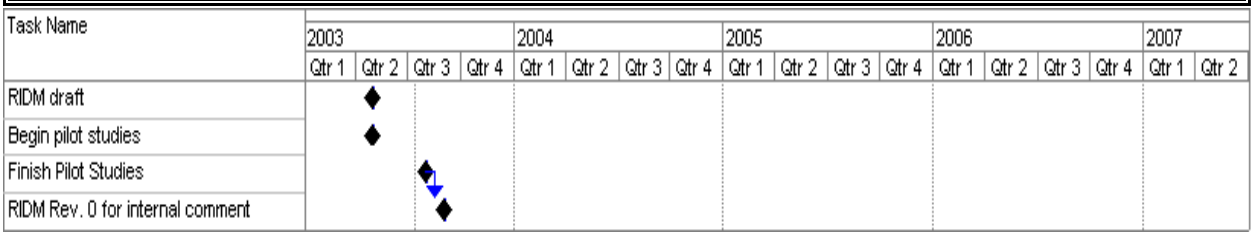
RTG with the assistance of BNL, is reviewing the eight case studies conducted during the Phase I effort for their suitability in testing the proposed process in the draft RIDM. Where applicable, the decision process used in the case studies would be compared to the proposed RIDM process. The preliminary findings were completed in August 2003.

NMSS Priority: Medium

Project Considerations: The pilot studies will help test the risk-informed decisionmaking guidance to get a better understanding of how any proposed risk goals or guidelines fit into the overall risk-informed decisionmaking process.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
RIDM draft			April 2003
Begin Pilot Studies			April 2003
Finish Pilot Studies	September 2003		
RIDM Rev. 0 for internal comment	December 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-EER1-7 Materials Safety Arena

Implementation Activity: Develop Human Reliability Analysis Capability Specific to Materials and Waste Applications

(Lead Organization: NMSS/RTG and RES)

Primary Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic. (EER)

Strategy: We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)

NMSS sent a User Need Memo to RES on February 3, 2003, requesting research assistance in developing human reliability analysis capability specific to materials and waste applications. Initially, RTG recognized the need to identify and develop a simple method of incorporating human factors and estimating human reliability for the wide range of situations and activities encountered and performed by NMSS licensees.

In response to the NMSS User Need Memo, RES has initiated a feasibility/scoping study to identify NMSS needs. This study is expected to be completed by the end of FY 2003. On the basis of this study, RES plans to develop HRA methods and tools for risk-informed applications in the Materials Safety Arena.

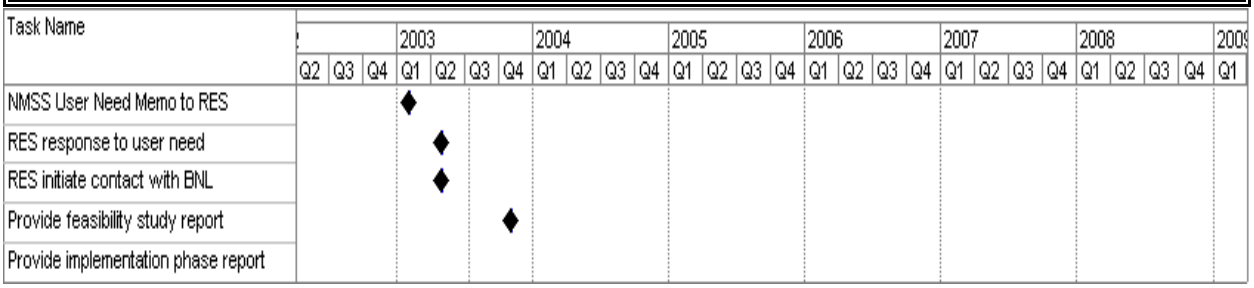
Similar work is also being performed in-house by RES in the Waste Safety arena.

NMSS Priority: Medium

Project considerations: In Phase 2, HRA methods, data, tools, and guidance are to be developed, as necessary, on the basis of the feasibility phase results. This work implementation phase is expected to begin in FY 2004.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
NMSS User Need Memo to RES			February 2003
RES response to user need			April 2003
RES initiate contract with BNL			May 2003
Provide feasibility study report	October 2003		
Provide implementation phase report	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-EER2-1 Materials Safety Arena

Implementation Activity: Multi-phase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations)

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will identify, prioritize, and modify processes based on effectiveness reviews to maximize opportunities to improve those processes. (EER2)*

The staff used the risk information in NUREG/CR-6642, along with supplemental records from the underlying database, in its review of the "Mallinckrodt Lessons Learned" and the possible subsequent revision of the Inspection and Licensing Guidance. Previously NMSS had established two task groups (Phase I and Phase II) to review the materials licensing and inspection program and provide recommendations. Phase I reviewed findings of the Mallinckrodt inspections in Region I and Region III that involved overexposures 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 have used the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

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

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.

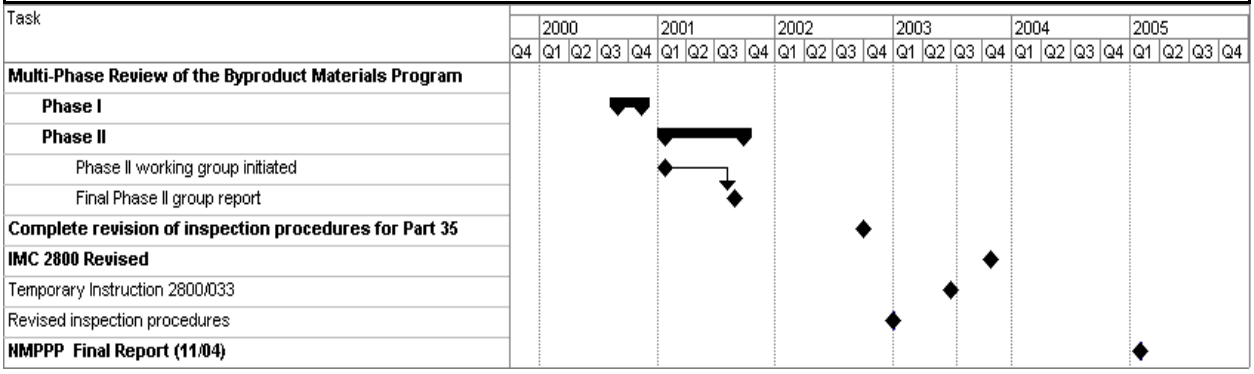
NMSS Priority: High

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 developed a 15-month pilot program. Risk information was used to identify certain categories of licenses for which the inspection intervals have been lengthened. Consequently, fewer routine inspections will be scheduled because some inspections that would have been completed during the next 15 months will be rescheduled for future years. However, the current practice of reducing the inspection interval for an individual licensee exhibiting a trend of poor performance will continue. Other revisions to IMC 2800 are consistent with a more performance-based inspection style, including the manner in which inspectors prepare for and document the results of routine inspections. The 11 inspection procedures, IP 87110 through IP 87120 associated with IMC 2800, were revised and redesignated as IP 87121 through IP 87127 for non-medical types of use and IP 87130 through 87134 for medical types of use. The revised inspection procedures were implemented in conjunction with the revised IMC 2800/033.

The pilot program was incorporated into the National Materials Program Pilot Projects Implementation Plan. The final report is due to the Commission in November 2004.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Final Phase I group report	November 2000		November 2000
Final Phase II group report	August 2001		August 2001
Complete revision of inspection procedures for Part 35	Summer 2002		October 2002
IMC 2800 Revised	July 2003	Sept 2003	
1. Temporary Instruction 2800/033	April 2003	July 2003	July 2003
2. Revised inspection procedures	October 2002	January 2003	January 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS) All four performance goals will be advanced.*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The staff has been conducting 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 has been an assessment of potential and likely doses to workers and 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 draft rulemaking plan, "Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements," which was provided to the Commission in SECY-02-0196 (November 1, 2002). The rulemaking would revise the exemptions from licensing in Part 30 and the requirements for exempt distribution in Part 32 to make the controls more commensurate with the potential doses associated with the various exemptions. It would also establish one or more new exemptions to reduce regulatory burden related to the use of some products with low associated risks and make the regulations more flexible, user-friendly, and performance-based for requirements for distributors of generally licensed devices. Staff proposed that the results of the systematic reevaluation of the exemptions with respect to the regulation of source material would be addressed in a separate rulemaking addressed in SECY-01-0072, Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License, April 25, 2001. The staff is currently compiling supplement information to SECY-01-0072, as directed by the Commission.

NMSS Priority: High

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

The Working Group includes members from NMSS, Region IV, OGC, OSTP, RES, and OE.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Recommendations from the Systematic Assessment of Exemptions and the Rulemaking Plan to Commission	June 2002	October 2002	October 2002
Proposed rule to EDO	18 months after SRM on rulemaking plan		
Final rule to EDO	12 months after proposed rule published		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

Task Name	2002				2003				2004	
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2
Exemptions from licensing and distribution of byproduct material: licensing and reporting requirements.				▼						
Recommendations from the Systematic Assessment of Exemptions and Rulemaking Plan to Commission				♦						

MS-MS2-1 Materials Safety Arena

Implementation Activity: Materials Licensing Guidance Consolidation and Revision

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework. (MS2)*

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 twenty volumes of "Consolidated Guidance about Materials Licenses" (NUREG-1556).

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

The following volumes of NUREG-1556 are scheduled for completion/review/revision in FY03 and FY04.

Vol. 2	Program-Specific Guidance About Radiography Licenses
Vol. 3	Applications for Sealed Source and Device Evaluation and Registration

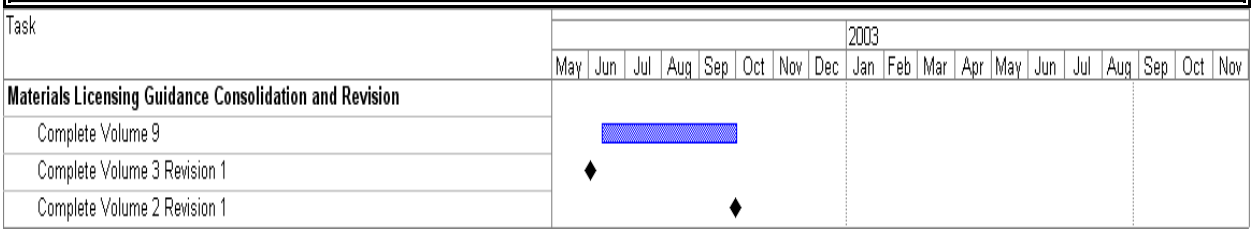
In FY 02 IMNS proceeded with licensing and inspection guidance to make it more risk-informed and performance based to fulfill a February 2002 commitment to the Congress. NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses," was published as final in October 2002 and Appendix BB to NUREG-1556, Vol. 9, was published as final in January 2003. This document provides guidance to the public and staff for licensing under 10 CFR Part 35, "Medical Use of Byproduct Material." Part 35 was issued on April 24, 2002, with an effective date of October 24, 2002.

NMSS Priority: Priority will be established based on the recommendations from the Phase II report of the Multi-phase Review of the Byproduct Materials Program activity and rulemakings.

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

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete Vol. 9	Summer 2002		October 2002
Complete Vol. 3 Revision 1	Summer 2003	Winter 2004	
Complete Vol. 2 Revision 1	Fall 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-MS2-3 Materials Safety Arena

Implementation Activity: Implementation of Part 70 Revision

(Lead Organization: NMSS/FCSS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategies: *We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework. (MS2)*

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

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

In December 2001, FCSS staff, along with the RTG and Part 70 stakeholders, finalized a Standard Review Plan to implement the requirements of Subpart H. This guidance document, which was published in March 2002, will assist the licensees in conducting ISAs and the staff in reviewing ISA documentation. The NRC staff has also developed, and is in the process of developing, other guidance documents related to Subpart H.

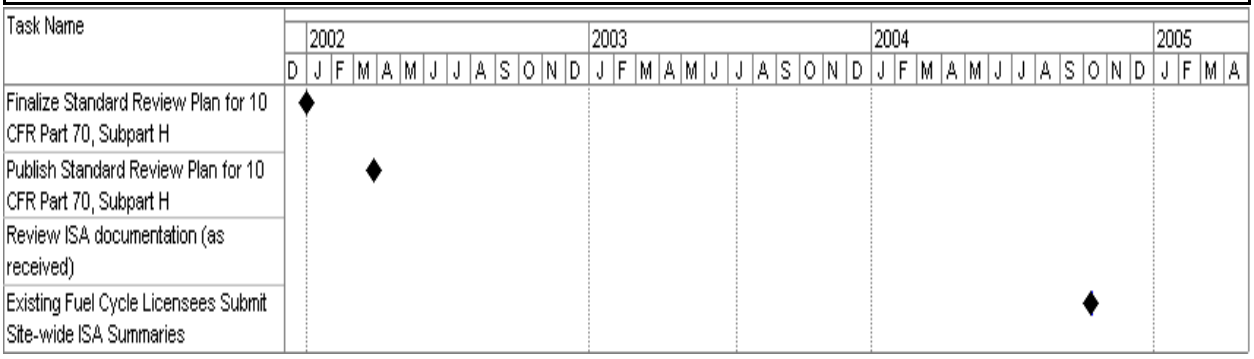
The staff has begun conducting ISA summary reviews for individual amendment requests. The staff anticipates conducting more detailed site-wide ISA documentation reviews in FY03, FY04, and FY05 for six operating uranium fuel fabrication facilities.

NMSS Priority: Medium

Project Considerations: The staff is working with stakeholders to identify lessons learned from the reviews of ISA summaries developed in support of license amendment requests. These lessons learned will be used to enhance the guidance for reviewing the facility-wide ISA summaries that existing 10 CFR Part 70 licensees are required to submit by October 2004. This activity is related to enhancing external communications in that several stakeholders are involved, including NEI and the licensees.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Finalize Standard Review Plan for 10 CFR Part 70, Subpart H			December 2001
Publish Standard Review Plan for 10 CFR Part 70, Subpart H			March 2002
Review ISA documentation	as received from licensees		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



MS-RB1-1 Materials Safety Arena

Implementation Activity: Revise Part 36: Panoramic Irradiators (PRM-36-01)

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders. (RB)*

Strategies: *We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden. (RB1)*

We will improve and execute our programs and processes in ways that reduce unnecessary costs to our stakeholders. (RB2)

The staff used the risk information in "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (NUREG/CR-6642) in its analysis of the "Petition for Rulemaking," PRM-36-1, which requests modification of 10 CFR 36.65(a) and (b). These regulations describe how an irradiator must be attended to allow for the operation of a panoramic irradiator with qualified operators on site. The staff, with the assistance of a contractor, conducted a specific risk assessment associated with the presence of an onsite operator by using the models and information found in NUREG/CR-6642. In addition, a survey was conducted on historical irradiator accidents worldwide that may have been attributed to the presence or lack of an onsite operator. Based on the results of the risk assessment and the findings of the survey, the staff prepared a draft rulemaking plan to amend the regulation using a risk-informed approach. *Due to the 9/11 event, the rulemaking activity was put on hold pending an NRC-wide vulnerability evaluation.*

NMSS Priority: Medium

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Draft Rulemaking plan to EDO	August 2001	September 2001	September 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

										2002										
Task	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Revise Part 36: Panoramic Irradiators (PRM-36-01)																				
Rulemaking plan to EDO							♦													

MS-RB1-2 Materials Safety Arena

Implementation Activity: **Revise Part 34: Radiography (PRM-34-05)**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders. (RB)*

Strategies: *We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden. (RB1)*

We will improve and execute our programs and processes in ways that reduce unnecessary costs to our stakeholders. (RB2)

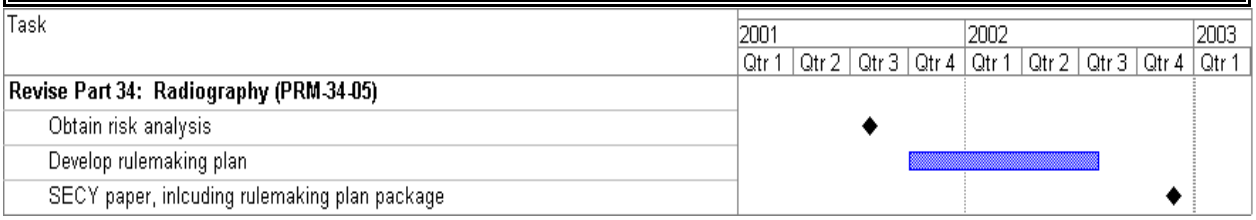
PRM-34-05 requests deletion of the term "associated equipment" from 10 CFR Part 34. This would essentially remove associated equipment from consideration under 10 CFR 32.210(c) and 30.32(g), which require radiation safety evaluation and registration of sealed sources and devices. The staff sent a denial package to the Commission on November 13, 2002 (SECY-02-0202). The Commission approved the staff's recommendation to deny the petitioner's request subject to the staff revising guidance and inspection procedures and issuing a Regulatory Issues Summary to align NRC's guidance and practice with the applicable regulations. The Commission disapproved the draft FRN, letter to the petitioner, and letters to Congress; and directed the staff to consult with OGC in revising these documents. The revised denial package was submitted to the Commission on May 29, 2003 (SECY-03-0088).

NMSS Priority: High

Project Considerations: The staff recommends no rulemaking because the existing requirements are appropriate. However, the staff recommends that in order to reduce unnecessary regulatory burden for licensees, the NRC, and the Agreement States, NRC guidance should be revised to clarify that safety critical components of an industrial radiography system must be evaluated under the registration process for sealed sources and devices, but associated equipment need not be registered. The proposed denial of the petition will emphasize the risk-informed and more performance based approach.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Obtain risk analysis	July 2001		July 2001
SECY Paper with a proposed denial of PRM-34-05	July 2002		November 2002
Revised denial package (SECY-03-0088)	May 2003		May 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



WS-MS1-1 Waste Safety Arena

Implementation Activity: **Probabilistic Risk Assessment of Dry Cask Storage Systems**

(Lead Organizations: NMSS/SFPO and RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

SFPO and RES staff has initiated a spent fuel dry storage cask probabilistic risk assessment (PRA). These PRA studies (Phase I & II) are intended to accomplish the following objectives: (a) provide methods for quantify the risks of dry cask storage of spent nuclear fuel, (b) provide insights for decisionmaking and improving 10 CFR Part 72 regulatory activities, and (c) provide analytic tools that can be used to implement future waste risk guidelines and risk-informed regulatory activities. This effort will also be part of the overall collaborative effort to develop a framework for incorporating risk information in the NMSS regulatory process (see MS-EER1-1). (Phase I): In February 2003, Research completed a draft pilot PRA on dry cask storage with a specific design. The draft report is under peer review and will be discussed with the joint ACRS/ACNW Committee in approximately September 2003. The final pilot PRA is planned to be published in 2004. (Phase II): Additional studies are being identified to broaden the application of the pilot PRA and develop additional PRA tools and risk insights.

NMSS Priority: High
RES Priority: 10.5

Project Considerations for Phase I: This activity requires technical assistance and development of analytical and calculational methods. Completion of the analyses will help SFPO explain the basis for review methodology and design acceptance criteria.

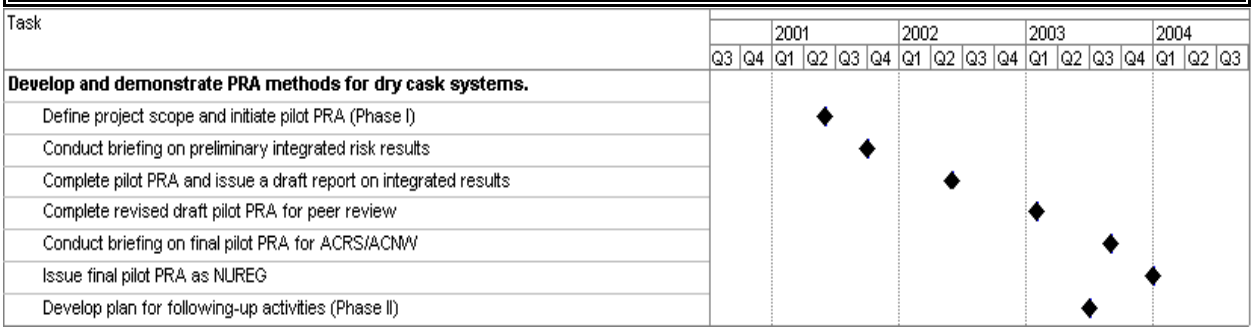
SFPO staff are taking PRA training presently offered through the TTC (see MS-EER1-2). Additionally, selected technical staff will be trained on the specific codes and methods employed in conducting this activity.

NMSS has developed a communication plan for the high level waste program (ADAMS Accession #ML003753322) which explicitly addresses dry cask storage systems. SFPO has also developed a communication plan for public interactions involving ISFSIs (ADAMS Accession# ML020990496), with an emphasis on the clear identification of the risk significance of ISFSIs.

Project Considerations for Phase II: Under development.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Define project scope and initiate pilot PRA (Phase I)			June 2000
Conduct briefing on preliminary integrated risk results	November 2001		November 2001
Complete pilot PRA and issue a draft report on integrated risk results	April 2002	June 2002	June 2002
Complete revised draft pilot PRA for peer review	December 2002	April 2003	February 2003
Conduct briefing on final pilot PRA for ACRS/ACNW	November 2002	October 2003	
Issue final pilot PRA as NUREG	2004		
Develop plan for follow-up activities (Phase II)	May 2003	July 2003	July 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



WS-MS1-2 Waste Safety Arena

Implementation Activity: **Incorporate Risk Information into the Decommissioning Regulatory Framework.**

(Lead Organization: NMSS/DWM)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

In 2002, the staff implemented a change in staff regulatory oversight of decommissioning commercial nuclear reactor plants, whereby the responsibility for project management will be transferred from NRR to NMSS earlier in the decommissioning process, to take advantage of NMSS's regulatory expertise in overseeing decommissioning and waste storage facilities. This should result in a more efficient and effective approach that maintains safety while increasing public confidence and reducing unnecessary regulatory burden on reactor licensees. As an adjunct to this effort, staff risk-ranked the requirements of the decommissioning inspection program and revised IMC 2561 to better align the reactor core inspection requirements with the risks associated with decommissioning power reactors.

NMSS is currently finalizing its review of all decommissioning policy and guidance documents for (1) efficiency, use of a streamlined approach, and user-friendliness of the processes described in the documents; and (2) the use of risk-informed, performance-based (RIPB) techniques, or risk-informed, less-prescriptive techniques, in the processes described in the documents. The goal of the policy and guidance review is to apply RIPB techniques to NMSS's decommissioning process as much as possible. For this, NMSS will use the guidance and experience developed through (1) the "Business Project Redesign" policy and guidance review and consolidation process for byproduct material licensing (NUREG-1556 series); (2) the experience gained with risk-informing the dose modeling guidance while working on the NMSS Decommissioning SRP (NUREG-1727); and (3) the ongoing evaluation of new and different approaches to the decommissioning review process that was stipulated in the SRM on decommissioning non-reactor facilities (DSI-9).

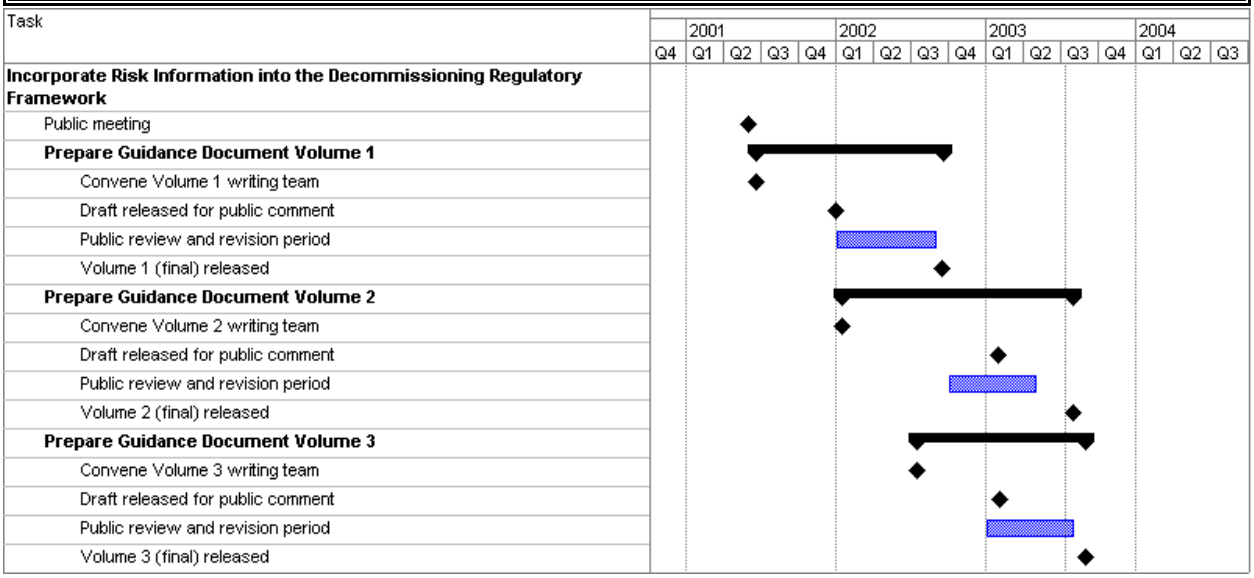
NMSS is consolidating and updating the policies and guidance of its decommissioning program, including existing NMSS decommissioning guidance documents, decommissioning technical assistance requests, decommissioning licensing conditions, and all decommissioning generic communications issued over the past several years. The goal is to produce consolidated NMSS decommissioning guidance that allows the NRC staff to evaluate information submitted by licensees in a timely, efficient, and consistent manner that protects public health and safety. The updated, consolidated guidance will be generally accessible to staff, licensees, and others, in hard-copy and/or electronic media (e.g., web-based). Staff expects this will result in more complete license documents and will expedite the approval process for both applicants and reviewers. In FY03, staff will complete the three-volume NUREG series (NUREG-1757) that will address (1) the decommissioning process; (2) characterization, survey, and determination of radiological criteria; and (3) financial assurance, record keeping, and timeliness.

NMSS Priority: Low

Project Considerations: Consolidation of existing guidance will enhance staff and licensees ability to comply with NRC's decommissioning requirements and provide a clearer basis for the requirements. Convening the various writing teams is considered to be a critical path activity.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Hold a Public Meeting to discuss the project	June 2001	June 2001	June 2001
Convene the Volume 1 writing team	June 2001	June 2001	June 2001
Volume 1 (draft) released for public comment	November 2001	January 2002	January 2002
Volume 1(final) released	July 2002	September 2002	September 2002
Convene the Volume 2 writing team	January 2002	January 2002	January 2002
Volume 2 (draft) released for public comment	June 2002	September 2002	September 2002
Volume 2(final) released	January 2003	September 2003	
Convene the Volume 3 writing team	July 2002	August 2002	August 2002
Volume 3 (draft) released for public comment	December 2002	January 2003	January 2003
Volume 3(final) released	July 2003	September 2003	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



WS-MS1-3 Waste Safety Arena

Implementation Activity: **Incorporate Risk Information into the High-Level Waste Regulatory Framework.**

(Lead Organization: NMSS/DWM)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security.*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

In November 2001, the staff published in the Federal Register the final Yucca Mountain risk-informed, performance-based rule (10 CFR Part 63). The amendment to Part 63 was issued in October 2002 to define "unlikely event."

In July 2003, the NRC issued the Yucca Mountain Review Plan - Final Report as NUREG-1804, Revision 2. The revised review plan incorporates the final 10 CFR Part 63 requirements and comments received during the public review period. The review plan provides guidance to staff on implementing the risk-informed, performance-based regulations of 10 CFR Part 63. This guidance will ensure that licensing reviews are risk-informed and the proper level of effort is focused on areas important to the findings.

The staff is continuing the risk insights initiative, which was begun in FY02, to ensure a focus on the most important issues during the issue resolution process with DOE. The first phase of the activity concentrated on a communication and integration exercise that included many technical and performance assessment staff in the high-level waste program at the NRC and Center for Nuclear Waste Regulatory Analyses. A series of facilitated meetings, with each key technical issue team, helped staff to better understand the importance of issues and identify areas where additional risk information and training are needed.

Staff is currently developing a "risk insights baseline," which will provide an overall perspective for evaluating the risk significance of repository issues and systems down to the subsystem level. The risk insights final report will include the baseline and references to supporting quantitative analyses. The final report will also provide applications of risk terminology in the high-level waste program, a methodology for maintaining and updating the risk insights baseline, and guidance to the staff for using risk insights during issue resolution and in implementing a risk-informed review or a license application as put forth in the Yucca Mountain Review Plan.

The staff is continuing to refine its Total-system Performance Assessment (TPA) computer model by developing TPA version 5.0, to make the model more realistic and to improve the staff's ability to use the TPA code effectively during the potential regulatory review. The staff plans to conduct an iterative performance assessment to test proposed uses of the TPA code to support the implementation of the regulatory framework and develop new risk information and update existing risk information.

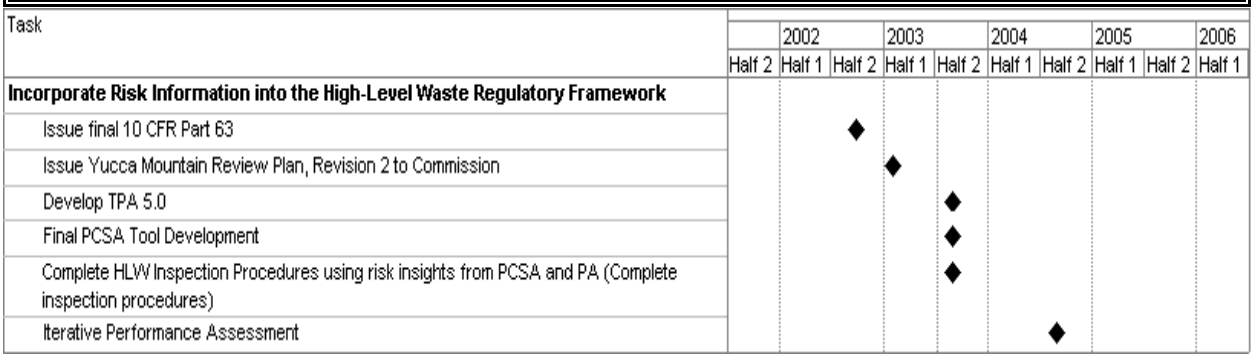
NMSS Priority: High

Project Considerations: Completion of the Yucca Mountain Review Plan will enhance the ability of the staff and a potential license applicant to understand and comply with NRC's Part 63 requirements. The review plan will also be used to explain to external stakeholders how the NRC would review a potential license application.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322).

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue Yucca Mountain Review Plan, Draft Revision 2 for comment.	September 2001		March 2002
Issue 10 CFR 63 Amendment			October 2002
TPA 4.1 Sensitivity Analysis, Rev. 1	December 2002		December 2002
Submit Yucca Mountain Review Plan, Final Revision 2, to the Commission	February 2003		March 2003
Issue Yucca Mountain Review Plan, Final Revision 2	30 days after Commission approval		July 2003
Develop TPA 5.0	September 2003		
PCSA Tool Development: Progress report/User's Manual Final PCSA Tool	 September 2003 September 2004		
Complete HLW Inspection Procedures using risk insights from PCSA and PA (Complete 4 inspection procedures)	September 2003		
Iterative Performance Assessment	September 2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



WS-MS1-4 Waste Safety Arena

Implementation Activity: **Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The NRC is amending its licensing requirements in 10 CFR Part 72 for dry cask modes of storage of spent nuclear fuel, high-level radioactive waste, and power reactor-related Greater than Class C (GTCC) waste in an independent spent fuel storage installation (ISFSI) or in a U.S. Department of Energy (DOE) monitored retrievable storage installation (MRS). This rule amendment will update the seismic siting and design criteria, including geologic, seismic, and earthquake engineering considerations. The amendments will make the NRC regulations that govern certain ISFSIs and MRSs more compatible with the 1996 amendments that addressed uncertainties in seismic hazard analysis for nuclear power plants. The amendments will allow certain ISFSI or MRS specific-license applicants to use a design earthquake level commensurate with the risk associated with an ISFSI or MRS.

NMSS Priority: High

Project Considerations: While no special training will be developed to complete this activity, implementation of this rulemaking may require additional training on the use of probabilistic seismic hazard analysis (PSHA) methods.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322), which explicitly addresses spent fuel storage and ISFSIs. SFPO has developed a communication plan for public interactions involving ISFSIs (ADAMS Accession#ML020990496), with an emphasis on the clear identification of the risk significance of ISFSIs.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Proposed rule to Commission (SECY-02-0043)			March 2002
Final rule to EDO	May 2003	June 2003	June 2003

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

Task	2002				2003		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Revise Part 72 -- Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs							
Proposed rule to Commission (SECY-02-0043)	◆						
Final rule to EDO						◆	