Attachment 3

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
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
DSI	direction-setting issue
EPA	Environmental Protection Agency
EPIX	equipment performance and information exchange
EPRI	Electric Power Research Institute
ET	executive team
FAVOR	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
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
RBPI	risk-based performance indicators
RES	NRC Office of 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)
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
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 decision-making.

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 cross-cutting 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 I. 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 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 decision-making 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 counter measures 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 draft screening criteria for identifying regulatory activities that could benefit from risk information. The draft screening criteria were published in Federal Register Notices (65 FR 14323, 03/16/00, and 65 FR 54323, 09/07/00). The criteria have been revised after consideration of comments received at workshops and public meetings and the staff's experience in their application. The revised draft screening criteria are as follows:

(1) Would 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 for the applicant or licensee?

(4) Would a risk-informed approach help to effectively communicate a regulatory decision or situation?

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

(5) Does information (data) and analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

If the answer to criterion 5 is yes, proceed to additional criteria; if not, the activity is considered to be screened out.

(6) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit? The net benefit will be considered to apply to the public, the applicant or licensee, and the NRC. The benefit to be considered can be improvement of public health and safety, improved protection of the environment, improved regulatory efficiency and effectiveness, improved communication to the public, and/or reduced regulatory burden (which translates to reduced cost to the public.)

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

(7) Do other factors exist (e.g., legislative, judicial, adverse stakeholder reaction) which would preclude changing the regulatory approach in an area, and therefore, limit the utility of implementing a risk-informed approach?

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

These draft selection criteria were developed by NMSS for use in the materials and waste arenas. The Risk Management Operating Team will evaluate the proposed final criteria to determine their applicability to the reactor arena.

3. Factors to Consider in Risk-Informed Regulation

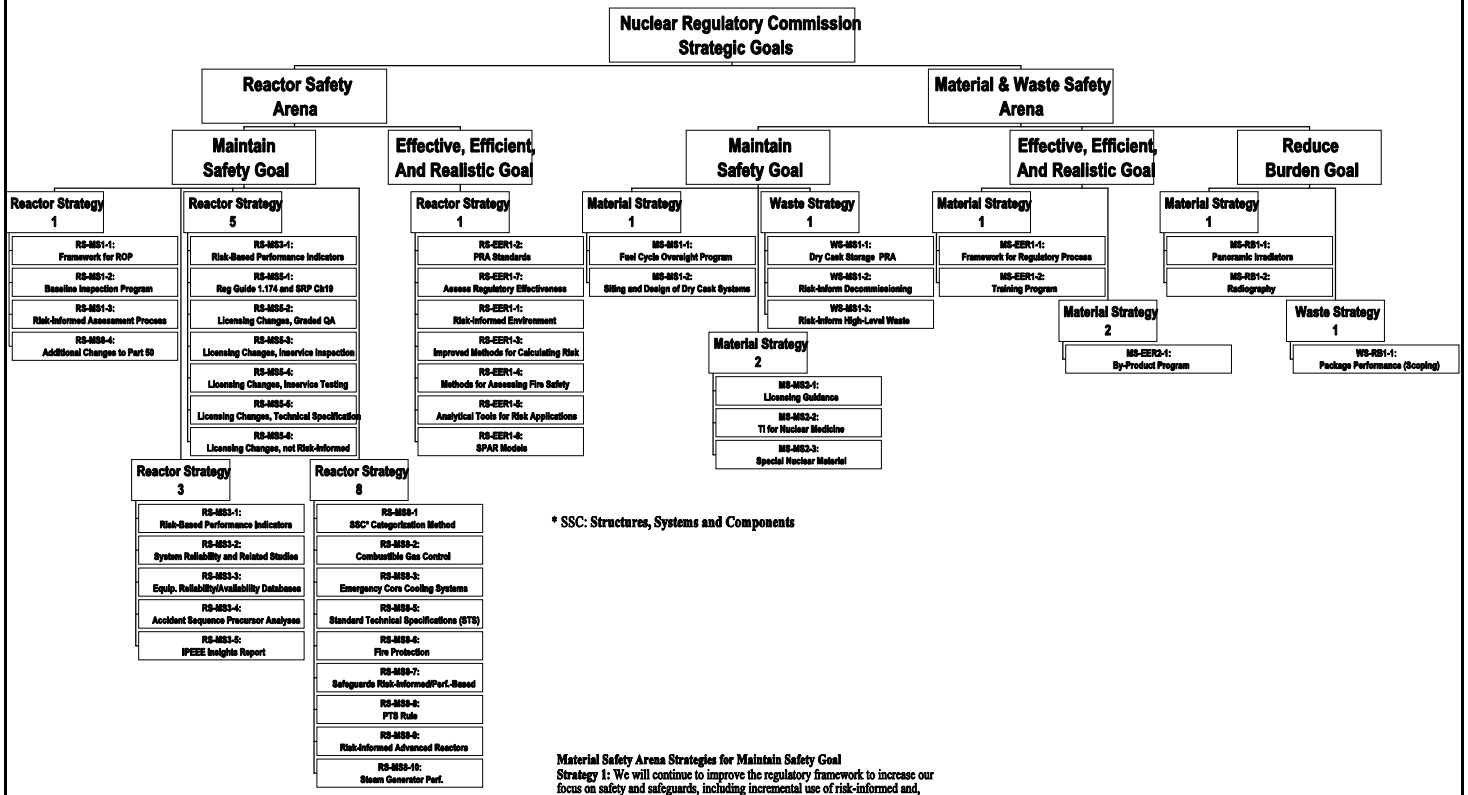
The NRC mission is to protect the public health and safety and protect the common defense and security in civilian applications of nuclear technology. Historically, the agency has used an effective, albeit often conservative, approach for regulatory decisions. To accomplish its mission, the agency has 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.

Figure 1

Risk-Informed Regulation Implementation Plan



* SSC: Structures, Systems and Components

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

Material Safety Arena Strategies for Maintain Safety Goal
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 for Effective, Efficient, and Realistic Goal
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 for Reduced Burden Goal
Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

Waste Safety Arena Strategies for Maintain Safety Goal
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 for Reduced Burden Goal
Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

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
- 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.

As a result of issues raised by the staff rulemaking effort for 10 CFR 50.44, the staff is reassessing its position on three factors: 1) voluntary alternatives versus mandatory requirements; 2) selective implementation; and 3) regulatory analysis. When these issues are resolved, future issues of the RIRIP will reflect changes, if any, to the staff considerations related to these three factors.

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, as well as the philosophy of a multiple-barrier approach 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 concept of defense-in-depth has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field. It is expected that defense-in-depth for reactors and nuclear materials (which includes activities involving 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, Regulatory Guide 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,
- an over-reliance on programmatic activities to compensate for weaknesses in equipment or device design is avoided,
- system redundancy, independence, diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers),
- the independence of barriers is not degraded such that 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 two models on the scope and nature of defense-in-depth. "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 Regulatory Guide 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; e.g.,
  - 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; e.g.,
  - the balance between prevention and mitigation?
  - the number of barriers?
  - the need for redundancy, diversity, independence of systems?
  - the events that need to be considered in the design?
- Do the defense-in-depth considerations expressed in Regulatory Guide 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?
- Is there over-reliance on programmatic activities 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, Regulatory Guide 1.174 states that acceptable risk-informed changes to a nuclear power reactor's licensing basis will be consistent with the principle that sufficient safety margins are maintained. Improved information from data analysis, research experiments, and the like suggest that excessive safety margins exist 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 foster 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 margin)?
- 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 a 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 might 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 of cancer risk (other than leukemia) was most consistent with the data. Consequently, licensees are expected to keep radiation releases to a level as low as reasonably achievable. In keeping with this philosophy of "as low as reasonably achievable," 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 safety goals for the materials and waste safety arenas similar to the reactor safety goals, and it is expected they will be used in a similar capacity.

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. SECY-00-0191 (dated September 1, 2000) lists high-level guidelines that are intended to promote the use of a performance-based regulatory framework throughout the agency. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn can result in a more efficient and effective regulatory process.

The staff plans to develop guidance to incorporate the high-level guidelines into internal NRC procedures and to apply the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities.

To the extent appropriate, staff activities to risk-inform regulations should also incorporate the performance-based approach to regulation. The corollary is also true; performance-based regulations should be risk-informed when possible. Figure 2 illustrates that both risk-informed and performance-based approaches will be pursued as appropriate when modifying the regulatory framework.

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?
- Can the risk-informed change be made as a performance-based change?

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 Part 50.109, the Commission's 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 risk-informed requirements or must implement them all. Currently, selective implementation is decided on a case-by-case basis.

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), or enforcement. The staff should consider the implications of risk-informed regulatory changes on regulatory oversight activities and ask of 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 evaluation risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework.

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 provide communication plans that will increase public confidence by 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 to this, the staff of NMSS prepared and submitted to the OEDO in December 2000 a communication plan for risk-informing the 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 methodology 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. NRR and RES intend to develop a similar plan for the reactor safety arena.

Over the past year, formal communication plans were also developed for several activity-specific programs, including the fuel cycle facility oversight process, high-level waste, the nuclear material inspection program, the reactor oversight process, reactor safeguards and security, and South Texas Project activities.

More information regarding the reactor oversight process plan and specific guidance for developing communications plans are provided in the following memoranda:

- Memorandum from William D. Travers, Executive Director for Operations, regarding Communication Activities, May 1, 2000.
- Memorandum from William D. Travers, Executive Director for Operations, regarding Next Steps Toward Completing Communication Plans, July 19, 2000.

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 is presented 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 narrative 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 presents a summary schedule for the current risk-informed regulation implementation activities in the reactor safety arena and in the materials and waste arenas. Figure 2 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 cross-cutting 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 in some way (or cross-cutting). 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 Performance-Based Indicators
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-4 ASP
- RS-MS3-5 IPEEE
- RS-EER1-6 SPAR Models
- MS-MS1-1 Fuel Cycle Oversight
- 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 Develop and implement risk-based performance indicators (RBPIs)
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-MS3-5 IPEEE
- RS-EER1-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-1 Develop and implement risk-based performance indicators (RBPIs)

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Equipment Reliability/Availability Databases

RS-MS3-2 Assess the risk significance of industry-wide operational events and data trends and conduct system reliability and related studies

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-MS3-4 ASP Analyses
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-3 Maintain databases to support the assessment of industry-wide equipment reliability and availability

- RS-MS1-3 Assessment Process
- RS-MS3-1 Risk-Based Performance Indicators
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-4 ASP Analyses
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-8 PTS Rule
- RS-MS8-10 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 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-4 Produce accident sequence precursor analyses of plant events (ASP Analyses)

- RS-MS1-1 Reactor Oversight Process
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-EER1-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-5 Review IPEEE submittals and issue insights report

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-9 Advanced Reactors
- RS-EER1-2 PRA Standards Development
- WS-MS1-1 Dry Cask PRA
- WS-MS1-3 High-Level Waste Regulatory Framework

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

- RS-MS3-5 IPEEE
- RS-MS5-2 Licensing Basis Changes: Updating Graded QA RG
- RS-MS5-3 Licensing Basis Changes: Inservice Inspection
- RS-MS5-4 Licensing Basis Changes: Inservice Testing
- RS-MS5-5 Licensing Basis Changes: Technical Specifications
- RS-MS5-6 Licensing Basis Changes: Non Risk-Informed Guidance
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- 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: Updating the Graded QA RG

- RS-MS5-1 RG 1.174 and SRP 19

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

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-8 PTS Rule Revision

RS-MS5-4 Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing

- RS-MS5-1 RG 1.174 and SRP 19

RS-MS5-5 Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications

- RS-MS5-1 RG 1.174 and SRP 19

RS-MS5-6 Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals

- RS-MS5-1 RG 1.174 and SRP 19

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 Equipment Reliability/Availability Databases
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development

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

- No cross-cutting 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-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 alternative requirements for safeguards that are risk-informed and/or performance-based

- WS-MS1-2 Decommissioning Regulatory Framework

RS-MS8-8 Develop the technical basis to revise the PTS rule

- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-MS5-3 Licensing Basis Changes: Inservice Inspection
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-9 PRA Review of advanced reactor applications

- RS-MS3-5 IPEEE
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-10 Develop methods for assessing steam generator performance during severe accidents

- RS-MS3-3 Equipment Reliability/Availability Databases
- 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-MS3-5 IPEEE
- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-3 Emergency Core Cooling Systems
- 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**
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

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

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-8 PTS Rule Revision
- RS-MS8-10 Steam Generators
- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-6 SPAR Models
- WS-MS1-1 Dry Cask PRA

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

- RS-MS3-3 Equipment Reliability/Availability Databases
- 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
- **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 Equipment Reliability/Availability Databases
- RS-MS8-10 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-6 SPAR Models
- WS-MS1-1 Dry Cask PRA

RS-EER1-6 Develop standardized plant analysis risk (SPAR) models for staff risk assessments

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-MS3-4 ASP Analyses
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-EER1-7 Assess regulatory effectiveness using risk information

- RS-MS1-3 Assessment Process
- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Equipment Reliability/Availability Databases
- RS-MS3-4 ASP Analyses

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
- **RS-MS1-1 Reactor Oversight Process**
- **RS-MS5-1 RG 1.174 and SRP 19**
- **RS-EER1-2 PRA Standards Development**

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 the Byproduct Materials Program (Mallinckrodt Lessons-Learned Review)

- MS-MS2-1 Materials Licensing Guidance
- MS-MS2-2 TI for Nuclear Medicine Program

MS-MS1-1 Revise Fuel Cycle Oversight Program

- RS-MS1-1 Reactor Oversight Process
- MS-MS2-3 Implementation of Part 70 Revision
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

MS-MS1-2 Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs

- **WS-MS1-1 Dry Cask PRA**

MS-MS2-1 Materials Licensing Guidance Consolidation and Revision

- **MS-EER2-1 Review of Byproduct Materials Program**

MS-MS2-2 Risk-informed, Performance-based Temporary Instruction for the Nuclear Medicine Program

- **MS-EER2-1 Review of Byproduct Materials Program**

MS-MS2-3 Implementation of Part 70 Revision

- **MS-MS1-1 Fuel Cycle Oversight Program**

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

- **No cross-cutting activities identified.**

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

- **No cross-cutting activities identified.**

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

- MS-MS1-2 Revise Part 72: Siting/Design of Dry Cask ISFSIs
- **RS-MS3-5 IPEEE**
- **RS-EER1-3 Improved Methods of Calculating Risk**
- **RS-EER1-4 Fire Safety Methods**
- **RS-EER1-5 Maintain Analytical Tools**

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

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-7 Safeguards

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

- **RS-MS3-5 IPEEE**
- **RS-MS5-1 RG 1.174 and SRP 19**

WS-RB1-1 Package Performance Study (Scoping)

- No cross-cutting activities identified.

Figure 1
Summary Schedule of Activities

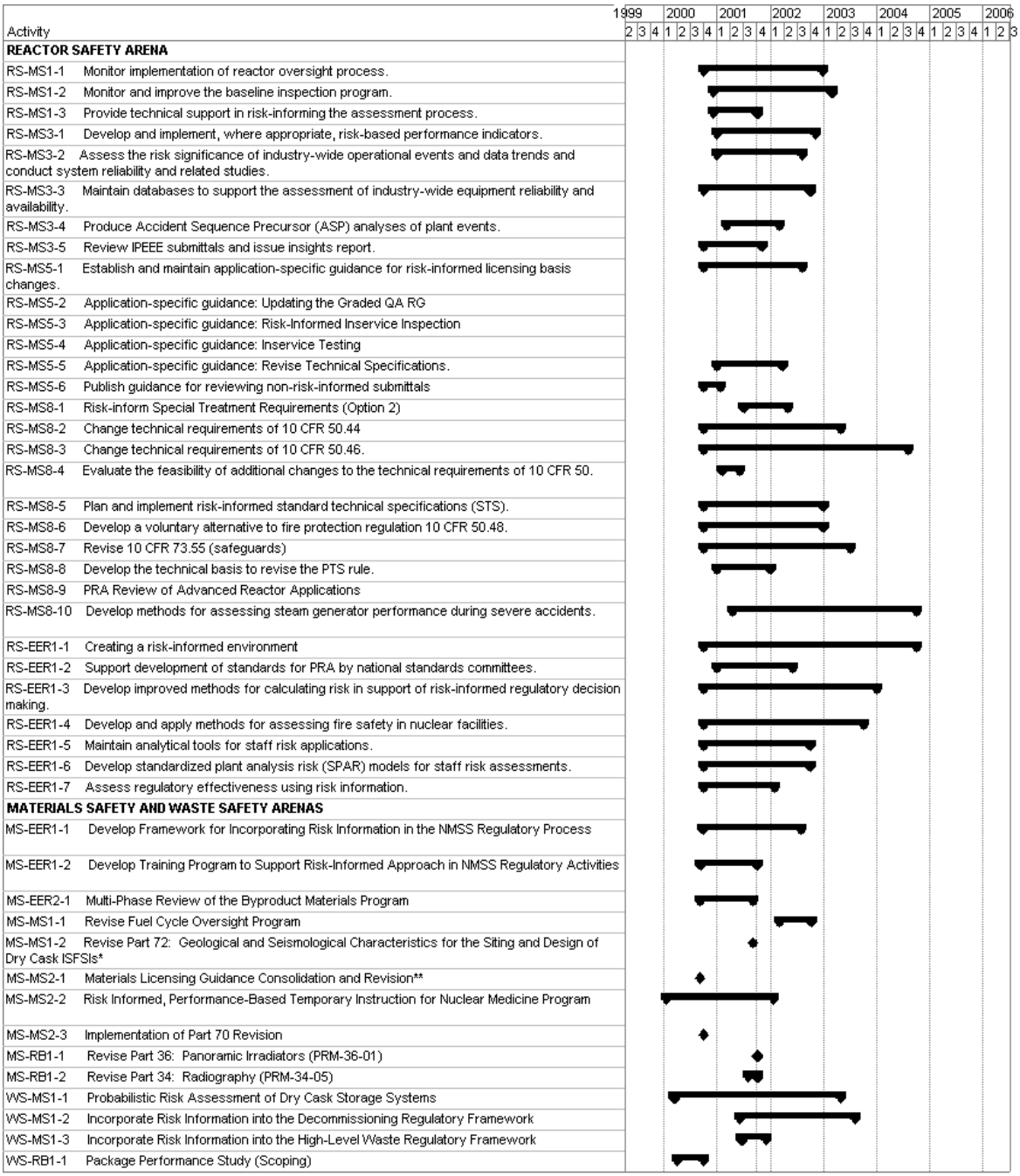


Figure 2

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Chapter 1. Reactor Safety Arena

William Kane, 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 non-probabilistic 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 there were the best opportunities for improvements. 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, as it is associated with the Commission's Strategic Plan, is provided later in this chapter.

One of 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 a 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 areas that presented burden and 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, in-service inspection, in-service testing, or 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.

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 involves 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 activities to enhance its capabilities to conduct or review risk analyses through various research programs. These include activities to improve tools, enhance data, and to 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(s) is listed under each implementation activity. The prioritization processes followed by NRR and RES management, although not the same, use the agency's strategic plan performance goals to prioritize Office activities as part of the budget process. The RES prioritization scores range from 1-10, with 10 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:

Reactor Safety Arena

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	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	Develop and implement, where appropriate, risk-based performance indicators (RBPIs)
RS-MS3-2	Assess the risk significance of industry-wide operational events and data trends and conduct system reliability and related studies
RS-MS3-3	Maintain databases to support the assessment of industry-wide equipment reliability and availability
RS-MS3-4	Produce accident sequence precursor analyses of plant events
RS-MS3-5	Review IPEEE submittals and issue insights report
RS-MS5-1	Establish guidance for risk-informed licensing basis changes: Update Regulatory Guide 1.174 and SRP Chapter 19
RS-MS5-2	Establish application-specific guidance for risk-informed licensing basis changes: Updating the Graded QA RG
RS-MS5-3	Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection
RS-MS5-4	Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing
RS-MS5-5	Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications
RS-MS5-6	Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals
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

Reactor Safety Arena

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 alternative requirements for safeguards that are risk-informed and/or performance-based

RS-MS8-8 Develop the technical basis to revise the PTS rule

RS-MS8-9 Develop the technical basis to support risk-informed review of advanced reactors

RS-MS8-10 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 decision making

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 Develop standardized plant analysis risk (SPAR) models for staff risk assessments

RS-EER1-7 Assess regulatory effectiveness using risk information

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).

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 new 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. Results and lessons learned from the first year of implementation of the new reactor oversight process are documented in SECY-01-0114 dated June 26, 2001.

NRR Priority: 11

Project Considerations: The revised 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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	30.7	0
2002	31.7	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Report on lessons learned from full implementation	6/2001		6/2001
Status report on lessons learned from implementation	3/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

	2000				2001				2002				2003			
Task	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Monitor implementation of reactor oversight process.																	

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.

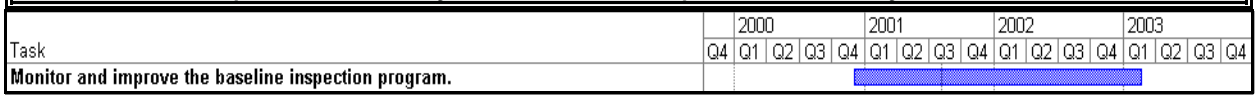
NRR Priority: 11

Project Considerations: The staff has develop a self-assessment process to continue to refine and improve the reactor oversight process to incorporate lessons learned and future risk insights.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.0	0
2002	2.0	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Generate analytical tool or method to support periodic inspection of licensees' corrective action programs	12/2000	12/2001	
Revise inspection procedures to incorporate lessons learned from initial implementation	1/2002		

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 updated as needed to support implementation of the program.

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 new reactor oversight program and other risk-informed initiatives. The task group consists of representatives from NRR, HR and the regions. The task group began meeting in July and August 2000 to plan its review.

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 risk-based performance indicators currently under development will reflect risk-significant changes in plant performance and will be used in the assessment process. Likewise, SPAR models support Phase 3 of the significance determination process.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	4.6	215
2002	4.7	300

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete report on assessment of the extent to which human performance is reflected in the reactor oversight process.	12/2000	8/2001	
Maintain and update significance determination process notebooks	9/2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

		2000				2001				2002			
Task	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Provide technical support in risk-informing the assessment process.													

Implementation Activity: **Develop and implement, where appropriate, risk-based performance indicators (RBPIs) (RES & NRR)**

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.*

The reactor oversight process (ROP) uses objective performance indicators and risk informed analyses of inspection findings to assess licensee performance. Risk-Based Performance Indicators (RBPIs) are being developed to improve performance indicators for potential implementation in the ROP. The potential RBPIs include:

- Reliability and availability indicators at the component, train, and system level;
- Indicators for shutdown modes and fire events that are consistent with current models, data, and methods;
- Plant-specific threshold values to reflect risk-significant differences in plant designs; and
- An overall-plant-performance indicator that will include the risk significance of individual RBPIs and inspection findings for a plant.

RES Priority: 7.0
NRR Priority: 6.0

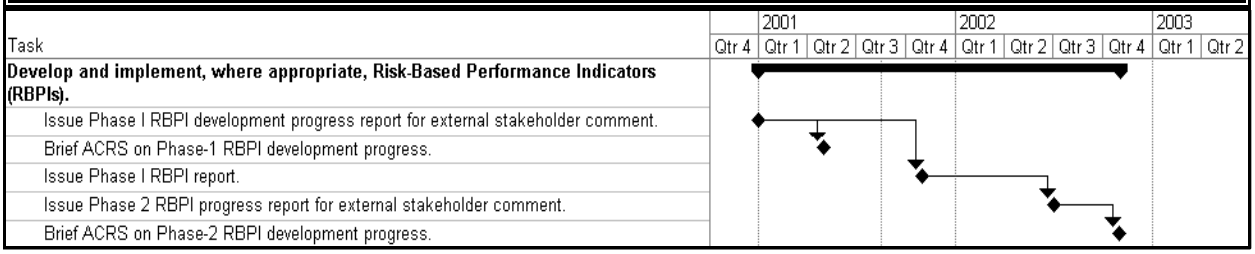
Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the development and reporting of RBPIs. The RBPIs will utilize information obtained from: (1) inspection reports and Standardized Plant Analysis Risk (SPAR) models; (2) 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 the Sequence Coding and Search System (SCSS) Licensee Event Report (LER) database, the Reliability and Availability Data System (RADS), the CCF database, and the Monthly Operating Report (MOR) database.

RBPIs 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 RBPIs will also be used by NRR's 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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.5 (RES) 0.2 (NRR)	700 (RES)
2002	2.0 (RES) 0.1 (NRR)	675 (RES)

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue Phase 1 RBPI development progress report for external stakeholder comment (RES)	1/2001		1/2001
Issue Phase 1 RBPI report (RES)	11/2001		
Determine what aspects of RBPI to consider for inclusion in ROP (NRR)	Fall 2001		
Issue Phase 2 RBPI development progress report for external stakeholder comment (NRR)	7/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Assess the risk significance of industry-wide operational events and data trends and conduct system reliability and related studies. (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.*

The RES staff performs studies to evaluate the functional reliability of risk-important safety systems and components in commercial nuclear power plants. These include 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 methods used in these studies are to: (1) obtain system unreliability estimates based on operating experience data and compare these estimates with the assumptions, models, and data used in PRAs and individual plant examinations (IPEs); and (2) review the operational data from an engineering perspective to determine trends and patterns and provide insights into failure mechanisms associated with the operation of each system. These studies provide information to improve the realism and credibility of the NRC's risk assessments that support regulatory decisions concerning plant-specific licensing requests, risk-informed inspection guidance, SDP evaluations, and resolutions of generic safety issues. Consistent with the PRA Policy Statement, system reliability studies also improve the realism of PRA by updating data available to be used in licensee-sponsored and NRC-sponsored PRAs and in the NRC's reviews of licensee PRAs. Finally, these studies contribute to identifying adverse industry trends, which is a strategic goal measure.

The risk-based analysis of reactor operating experience of systems, components, and events provide direct measurements of the performance (i.e., reliability and/or occurrence frequency) of risk-important safety features that are used to determine whether safety is improving, deteriorating, or remaining constant in light of NRC and licensee safety initiatives. The risk-based analyses are used by NRR's inspection staff in developing risk-informed inspection guidance - they provide analyses of trends and of leading contributors to unreliability for determining the most risk-significant items to inspect and whether more, less, or the same level of inspection is needed. The risk-based analyses are used by NRR's PRA staff to support the risk-informed review of licensee submittals - they allow reviewers of licensee submittals to identify substantial differences between license applications and the results of operating experience analyses, to more thoroughly review the areas having differences. They also are used by NRR in SDP evaluations - they provide trending data to determine if regulatory activities have achieved their desired impact. They are used by NRR and RES staff in their resolutions of generic safety issues. The risk-based analyses are used by the RES regulatory effectiveness staff to evaluate the effectiveness of NRC regulatory requirements, guidance, and processes using risk-important information. The analyses are also used by the RES operating experience and risk analysis staff in the development of SPAR models and RBPIs.

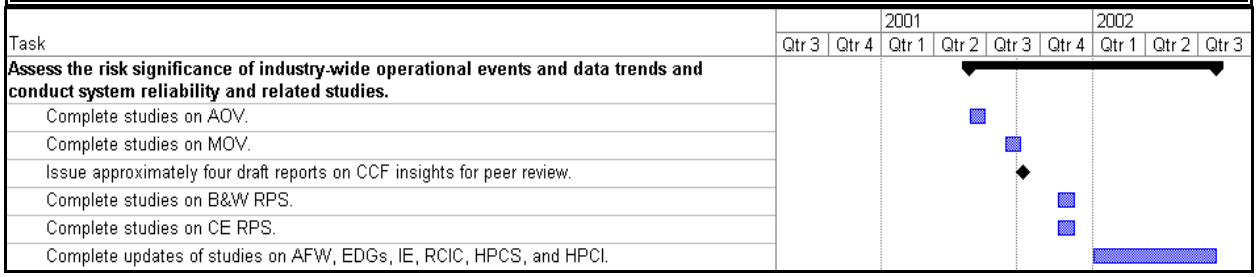
RES Priority: 6.4

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 the SCSS LER database, RADS, the CCF database, and the MOR database.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.3	978
2002	3.5	1400

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue approximately 4 draft reports on CCF insights for peer review	9/2001		
Complete system reliability and related studies on: • air-operated valves (AOV) • motor-operated valves (MOV) • B&W reactor protection system • CE reactor protection system	 6/2001 8/2001 11/2001 11/2001		6/2001
Complete updates of system reliability and related component studies on AFW, EDGs, IE, RCIC, HPCS, and HPCI	7/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Maintain databases to support the assessment of industry-wide equipment reliability and availability. (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.*

RES operates and maintains several databases which contain nuclear power plant operating-experience data. These databases include the SCSS LER database, RADS, the CCF database, the MOR database, and the ASP Events database. In addition, RES maintains access to the INPO EPIX database which is an input to RADS. The contents of these databases are summarized as follows:

- SCSS contains information about events at nuclear power plants in a computer-searchable framework based on the sequence-coding of information contained in LERs.
- RADS contains plant-specific and generic component-level data on reliability, and train and component level data on availability. (Includes input from EPIX).
- The CCF database 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 MOR database contains data on plant operations that are submitted by licensees via Monthly Operating Reports.
- The ASP Events database contains summary information of all the ASP events since 1969.

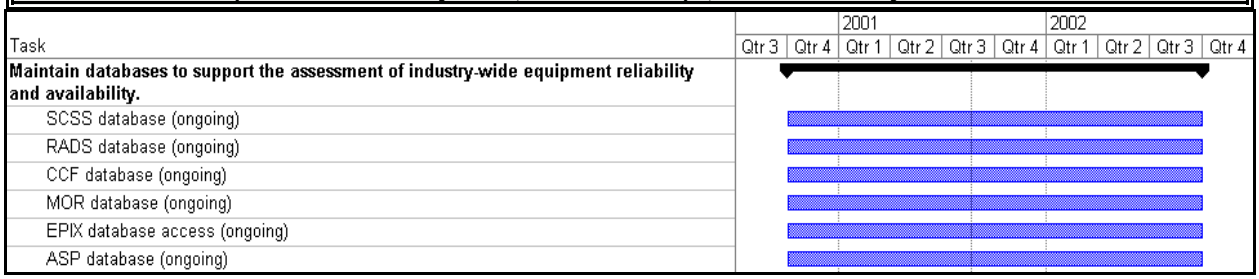
RES Priority: 9.6

Project Considerations: These databases provide the data for all RES operating experience analysis activities which include: (1) plant-specific event analyses reported (ASP analyses using 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) development of RBPIs.

In addition to providing the data for all RES operating-experience analysis activities, the databases are used by NRR's PRA staff in its risk-informed review of licensee submittals; by NRR in SDP evaluations; by NRR's inspection staff in developing risk-informed inspection guidance; and by the RES regulatory effectiveness staff to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes using risk-important information.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	2.0	1456
2002	3.0	1250

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Produce accident sequence precursor analyses of plant events (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.*

RES continues to operate the Accident Sequence Precursor (ASP) program. The primary objective of the ASP program is to systematically evaluate nuclear power plant operating experience using PRA methodology to identify, document, and rank those operating events or conditions that were most significant in terms of the potential for inadequate core cooling and core damage. In addition, the program has the following secondary objectives: (1) categorize the precursors for plant-specific and generic implications; (2) provide a measure that can be used to trend nuclear power plant core damage risk; and (3) provide a check on PRA-predicted core damage scenarios.

RES Priority: 9.6

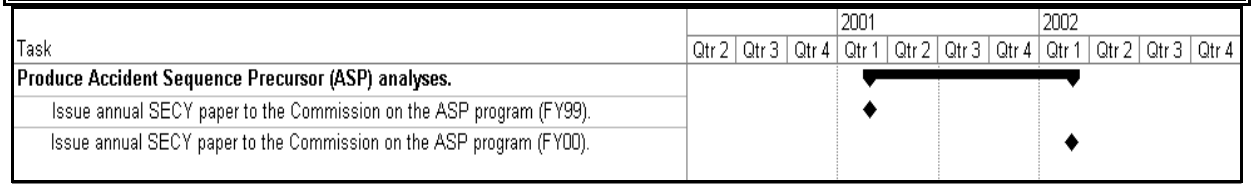
Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary to support the ASP program. ASP analyses utilize information obtained from: (1) inspection reports and SPAR models; (2) industry-wide analyses reported via initiating event 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 the SCSS LER database, RADS, the CCF database, and the MOR database.

NRR uses comparisons between ASP analyses and SDP assessments of inspection findings as part of their ROP self-assessment program. Trending information from the ASP program is part of the Agency's annual performance report to Congress. The ASP program provides the Commission with annual assessments of the significance of events/conditions occurring at commercial power plants and the trends in industry performance. This information will be part of the industry trending information used by NRR in accordance with SECY-01-0111.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.8	600
2002	3.0	625

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue annual SECY paper to the Commission on the ASP program	3/2001		3/2001
Issue annual SECY paper to the Commission on the ASP program	3/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Review IPEEE submittals and issue insights report. (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.*

The staff completed its review of the industry's Individual Plant Examination - External Events (IPEEE) submittals, issuing a draft insights report for public comment. The IPEEE program was a success that resulted in the nuclear power industry identifying safety improvements that substantially reduced the risk of accidents. Over 80% of the licensees have identified and implemented or proposed plant improvements to address concerns revealed through the IPEEE program. These voluntary licensee improvements have led to enhanced plant capability to respond to external events (such as earthquakes and floods) which can be important contributors to total plant core damage frequency. The generic insights from this effort will be used to support development of PRA guidance and standards, while plant-specific risk information will support the risk-informed reactor oversight program. The staff plans to formally close out its efforts related to the IPE/IPEEE programs via a paper for the Commission shortly after the final IPEEE insights report is published.

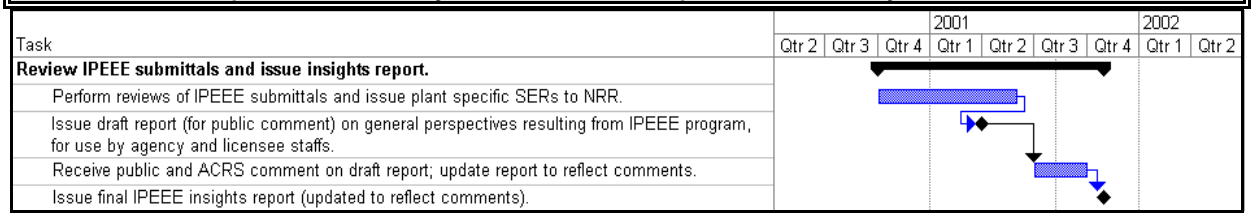
RES Priority: 9.6

Project Considerations: Insights derived from the IPE and IPEEE programs are being used by the staff in its review of license amendment requests and in the significance determination process used in the reactor oversight process.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	4.1	515
2002	0.3	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete review of IPEEE submittals	1/2001		1/2001
Issue draft report for public comments on general perspectives from IPEEE program	4/2001		4/2001
Issue final IPEEE insights report	10/2001		
Issue Commission Paper on completion of the IPE program	11/2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Establish guidance for risk-informed licensing basis changes: Update Regulatory Guide 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 issued.

NRC is conducting periodic reviews of these documents to identify any desired improvements. The first review, documented in a memorandum dated June 30, 1999, identified four topics for revision. The topics were (1) discussion of an ASME standard on PRA quality, (2) shutdown risk, (3) seismic margins method, and (4) clarification on fuel burnup and composition.

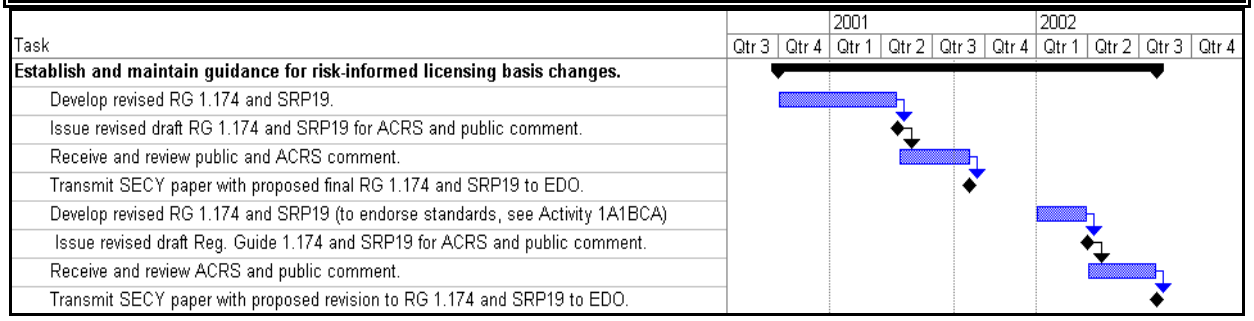
RES Priority: 8.4
NRR Priority: 6.0

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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1 (NRR) 0.2 (RES)	0
2002	<0.1 (NRR) 0.3 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Update RG 1.174 and SRP Chapter 19	8/2001	12/2001	
Second update of RG 1.174 and SRP Chapter 19	12/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: **Establish application-specific guidance for risk-informed licensing basis changes: Updating the Graded QA RG (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 graded QA RG 1.176 was issued in August of 1998. A GQA program was approved for the South Texas Project in November of 1997. Because the RG was issued after the pilot application was approved, it reflects the lessons learned from the pilot review.
While implementing the GQA pilot application, STP determined that they will derive much less benefit than they had anticipated from application of GQA. In particular, according to the licensee, special requirements in other regulations require continued complex and costly controls on many SSCs regardless of the reduced QA requirements. Consequently, there have been no further applications to apply GQA. In July of 1999, STP submitted a request for exemptions from many of the special treatment requirements, including greater relief from quality assurance requirements than allowed by the GQA program. The staff is utilizing this exemption request within the ongoing effort to risk-inform the special treatment requirements of 10 CFR Part 50 (see item MS8-1). Furthermore, a 10 CFR 50.54(a) rule change became effective April 26, 1999, that allows licensees to apply any QA program alternatives or exceptions approved by NRC staff for any other nuclear power plant (if the bases can be shown to be applicable at the plant making the change) without requesting prior staff review and approval. Finally, as discussed in the August 21, 2000 memorandum *Second Annual Review of the Application-Specific Risk-Informed Regulatory Guides and their Associated Standard Review Plans*, changes to application-specific RGs and SRPs will be initiated after proposed changes to RG 1.174 “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” and SRP Chapter 19 “Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance” are finalized. Changes to the application specific RGs and SRPs will include changes to increase conformance to the Revised RG 1.174 and SRP Chapter 19.

Therefore, changes to RG 1.176 will be not be performed until the staff's review of the STP exemption request is completed, further experience is gained with the effects of the 10 CFR 50.54(a) rule change on licensees' QA programs, and proposed changes to RG 1.174 and SRP chapter 19 are completed. Review of the STP exemption request is scheduled to be completed in August 2001, and changes to RG 1.174 and SRP Chapter 19 are scheduled to be completed in December 2001. Based on the current projected schedules, the staff anticipates that the effort to revise RG 1.176 would begin no sooner than Spring 2002.

NRR Priority: 10.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue revision for public comment to Graded Quality Assurance Regulatory Guide 1.176 to reflect update of RG 1.174 and SRP Chapter 19	Following update of RG 1.174 and SRP Chapter 19	TBD	

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 regulatory guide 1.178 and standard review plan Section 3.9.8 in September 1998. These documents provide guidance to licensees and staff regarding risk-informed (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. 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), 53 plants are expected to implement RI-ISI programs. The NEI also indicated that of the 53 RI-ISI submittals, 37 would be based on the EPRI methodology and 16 would be based on the WOG methodology. As of the end of May 2001, 39 plants have submitted their RI-ISI programs. The staff has approved 16 programs and the remaining 23 programs are currently under review.

The staff has not commenced work to revise RG 1.178 and SRP 3.9.8 since 1) the staff and the industry are still gaining experience with the implementation of the industry methodologies and 2) the three ASME Code Cases have not been finalized to incorporate lessons learned from the application of the methodologies.

NRR Priority: 10.0
RES Priority: 8.4

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue final Inservice Inspection Regulatory Guide 1.178 and SRP Chapter 3.9.8	12/2001		

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 Regulatory Guide 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 has recently 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. Also, the staff is developing a proposed rule 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 appropriate updating of the RI-IST program guidance.

NRR Priority: 10.0
RES Priority: 8.4

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

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 update of RG 1.174 and SRP Chapter 19	3/2002		

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 largely in the area of relaxations of allowed outage times for particular SSC.

The August 30, 1999, review of the guidance document identified one area for possible revision relating to the nexus of configuration risk management with the maintenance rule (50.65(a)(4)). The staff's activities related to risk-informing TS include several other initiatives discussed under another activity (see item MS8-5).

NRR Priority: 10.0
RES Priority: 8.4

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue revision for public comment to Technical Specifications Regulatory Guide 1.177 and SRP Chapter 16.1 to reflect update of RG 1.174 and SRP Chapter 19	3/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

				2001				2002			
Task	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Develop Revision to Technical Specifications Regulatory Guide 1.177 and SRP Chapter 16.1.											

Implementation Activity: Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals (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.*

As Policy Issue 4 in SECY-98-300 (Options for Risk-Informed Revisions to 10CFR Part 50), the staff recommended developing additional guidance with respect to the use of risk-informed approaches in regulatory activities. This guidance would be used in deciding if undue risk may exist when all other regulatory requirements appear to be met. SECY-99-246 (Proposed Guidelines for Applying Risk-Informed Decisionmaking in License Amendment Reviews) proposed interim guidance for applying risk-informed decisionmaking in the review of non-risk-informed license amendment requests. Central to the process is a determination as to whether the license amendment request, if granted, could create "special circumstances" under which plant operation may pose an undue risk to public health and safety even though all other regulatory requirements appear to be satisfied. The interim guidance was disseminated to the industry via Regulatory Issue Summary 2000-7.

The NRC plans to formally issue the guidance as a new appendix to Chapter 19 of the Standard Review Plan. A draft version of the appendix was published in the Federal Register for public comment on April 10, 2000, and the NRC held a public workshop to discuss the appendix on May 16, 2000. The staff discussed the draft appendix with the Advisory Committee for Reactor Safeguards (ACRS) and with the Committee to Review Generic Requirements (CRGR) and provided a final version of the appendix to the Commission on September 26, 2000. Provisions in the guidance on Commission notification were clarified in a November 13, 2000, memorandum (COMSECY-00-0038).

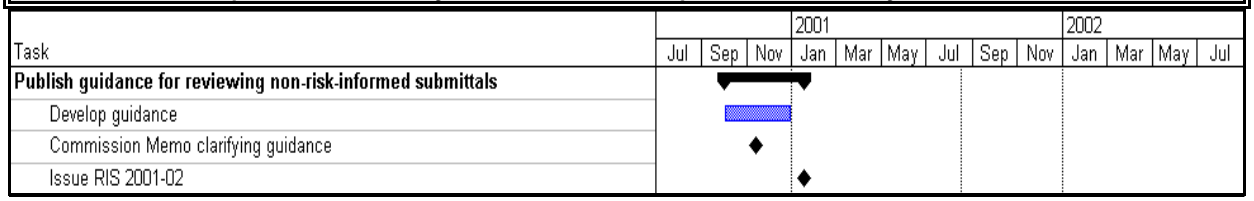
In the related SRM, the Commission approved the final guidance and approved its implementation in future reviews, subject to the clarification in COMSECY-00-0038 (, i.e., the staff will notify the Commission of the first few amendments judged to create special circumstances, and thereafter will use the Risk Informed Licensing Panel to provide a recommendation to upper management on whether Commission notification is appropriate). The NRC advised the industry of the final guidance via Regulatory Issue Summary 2001-02 (January 18, 2001). The final guidance will be issued as a new appendix to Chapter 19 of the Standard Review Plan and will also be reflected in the upcoming revisions of Regulatory Guide 1.174 and Office Letter 803.

NRR Priority:10.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1	
2002	<0.1	

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue guidance (RIS 2001-02) for special circumstances for use of risk-information in non-risk-informed licensing actions	11/2000		1/2001
Revise NRR Office Letter 803	9/2001		
Incorporate in revision to RG 1.174	12/2001		
Incorporate in Appendix to SRP Chapter 19	12/2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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. Since September 2000, the staff has been working with industry and interested stakeholders to resolve issues associated with industry-developed guidance intended to implement the rule. The staff is currently working to develop the proposed rule language, supporting regulatory information, and interacting with industry on pilot activities to test the implementing guidance.

The licensee for South Texas submitted an exemption request that would allow them to apply the concepts underlying this rulemaking (categorization, removal of special treatment requirements) at their facility, by receiving exemptions to certain existing requirements that would prevent them from otherwise undertaking such a program. The South Texas exemption was granted on August 3, 2001, and is considered to be a "proof-of-concept" prototype for the rulemaking. The exemption permits the licensee to implement an alternative treatment process that if effectively implemented by the licensee can result in safety-related low-risk significant (LRS) and non-risk significant (NRS) SSCs being capable of performing their safety functions under design-basis conditions throughout their service life. The staff has determined that the licensee's categorization process provides a reasonable method for determining that safety-related LRS and NRS SSCs have a small contribution to overall safety. The experience from the licensee's efforts and the staff review are being coordinated with the rulemaking activities and guidance development.

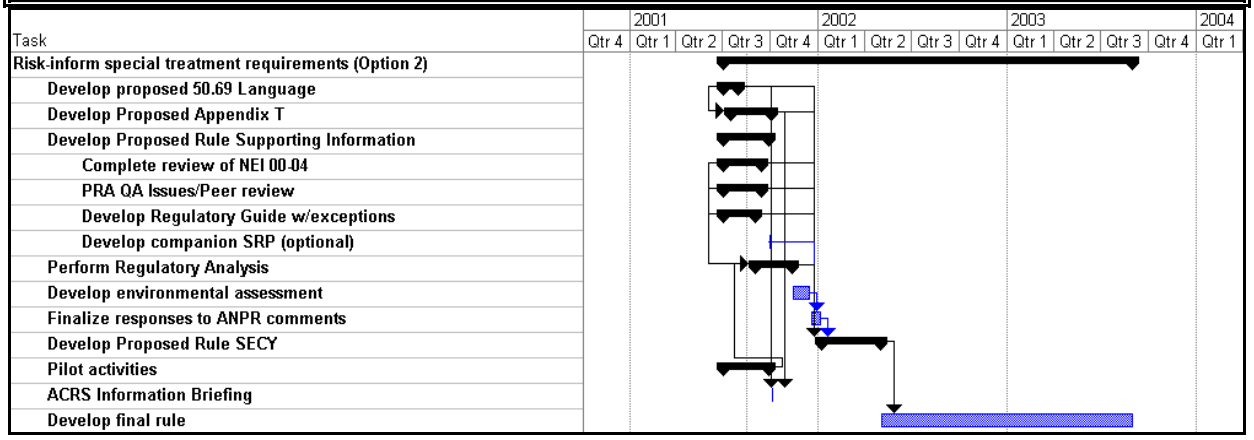
NRR Priority: 8

Project Considerations: The staff is currently working on developing Option 2 rule language; working with industry on NEI 00-04 implementation guidance; and interacting with industry on pilot activities. Challenges include translating the STP exemption lessons learned into the Option 2 framework; addressing the issue of PRA quality; and ensuring the framework can accommodate all facilities (existing, new, and renewed). The staff is applying insights from the STP exemption review into its rulemaking effort.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.0 (Option 2) 6.0 (STP)	12 (Option 2) 0 (STP)
2002	6.2 (Option 2)	350

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Rulemaking			
Proposed Rule	8/2001	4/2002	
Final Rule	12/2002	8/2003	
South Texas Project Exemption (Proof of Concept)			
Draft Safety Evaluation	11/2000		11/2000
Final Safety Evaluation to Commission	4/2001		6/2001
Pilot reviews			
Complete staff review of owners groups' submittals and	6/2001	10/2001	
NEI Guidance review			
Staff completes review of categorization/treatment/peer	6/2001	9/2001	

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. A SECY in response to the January SRM has been prepared by the staff and will be presented to the Commission shortly that provides information on (1) the status of technical work regarding the development of more realistic hydrogen source terms and the significance of seismically- and fire-initiated accidents, and (2) the establishment of Generic Issue 189 to assess the costs and benefits of possible additional hydrogen control requirements for PWR ice condenser and BWR Mark III containment designs. The staff also requested the Commission's approval to proceed with rulemaking.

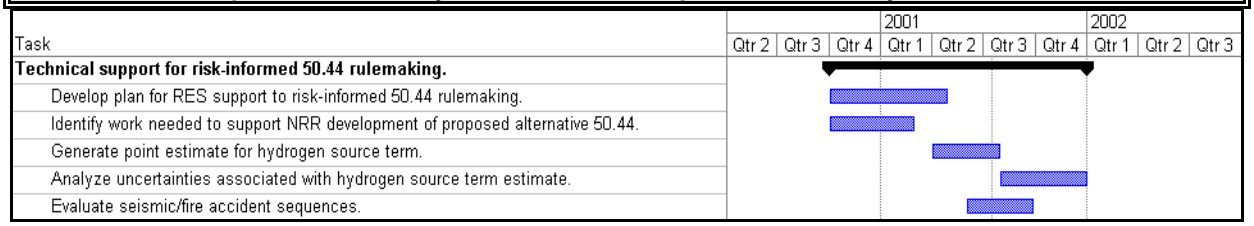
RES Priority: 8.4
NRR Priority: 8.0

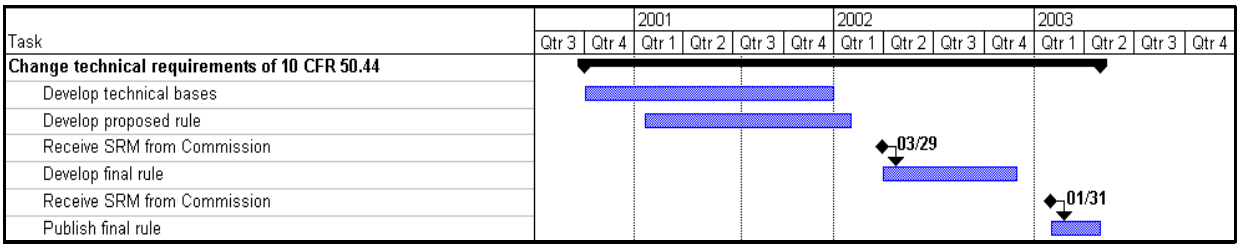
Project Considerations: As the first rule using the framework document developed for identifying and assessing candidate Part 50 changes, the development of schedules and resource requirements was subject to large uncertainties. Future changes to Part 50 are expected to be more resource efficient. Nevertheless,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

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.1 (NRR) 1.0 (RES)	97 (NRR) 300 (RES)
2002	3.0 (NRR) 0.5 (RES)	0 (NRR) 250 (RES)

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Proposed rulemaking to change 50.44 (NRR)	1/2002		
Final rulemaking (NRR)	6 to 9 months after SRM for proposed rule		
Estimate hydrogen source term (RES) Point estimate Uncertainties	 7/2001 12/2001		7/2001
Evaluate seismic/fire accident sequences	9/2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year





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-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.

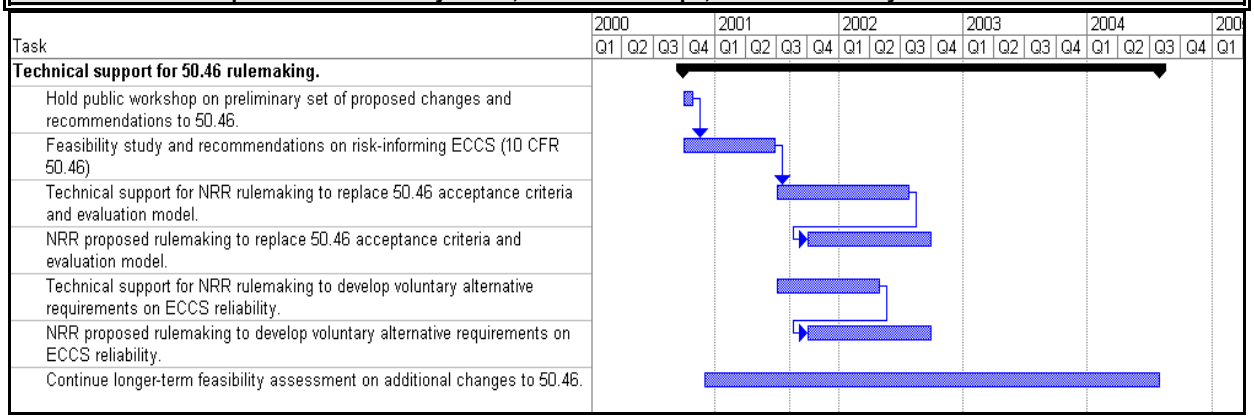
The staff concluded that it is feasible to change the technical requirements of 10 CFR 50.46 and has recommended to the Commission in SECY-01-0133 that the requirements be changed via the rulemaking process. The staff is now performing technical studies to help define the technical content of the rule change, and, upon the approval of the Commission, will begin rulemaking.

RES Priority: 8.4
NRR Priority: 6.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.6 (NRR) <0.1 (RES)	201 (RES)
2002	4.0 (NRR) 1.8 (RES)	750 (RES)

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Develop proposed rule to replace current prescriptive ECCS acceptance criteria and revise requirements for evaluation model	12 months after SRM or 2 months after development of technical basis (whichever is later)		
Develop technical basis for rule change	7/2002		
Develop proposed voluntary alternative requirements to ensure ECCS reliability commensurate with the frequency of challenge	12 months after SRM or 2 months after development of technical basis (whichever is later)		
Develop technical basis for rule change	4/2002		
Conduct feasibility assessment of additional changes to 50.46, including rigorous analysis of LOCA frequencies	9/2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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 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.

As discussed previously, the staff has concluded that it is feasible to change the technical requirements of 10 CFR 50.44 and 50.46. The staff will continue to solicit additional input on potential changes to the Part 50 technical requirements in public meetings and workshops. Subject to availability of resources, the staff will evaluate the feasibility of additional changes to the technical requirements.

RES Priority: 6.6

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.8	200
2002	0.2	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	6/2001		7/2001
Conduct public workshop to solicit suggestions	12/2001		
Provide recommendations and feasibility of changes to other rules	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

Task	2001						2002		
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3
Assess/prioritize additional risk-informed and performance-based changes to Part 50.									
Provide recommendations and third status report on other Part 50 changes to Commission.									
Periodic status report (fourth) on Part 50 Option 3.									
Plan and schedule for completion of Option 3.									

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

Project Considerations: The staff has completed its review of initiative 2 and is nearing completion of its review of initiative 3. A schedule for the review of the rest of the initiatives is currently being revised, however, as the staff works with the industry to review the relative priority of all technical specification submittals. The staff is developing a plan and will seek stakeholder comments on it in early fall. In addition, the staff recognizes that a consistent regulatory posture needs to be maintained between the related reliability requirements of 10 CFR 50.46, maintenance rule implementation, and technical specifications.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.0	0
2002	1.2	0

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

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

Task	2000				2001				2002				2003			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Plan and implement risk-informed standard technical specifications (STS).																

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 is currently working with the industry to resolve concerns regarding NFPA 805 and the proposed rulemaking that would endorse NFPA 805 as a voluntary alternative to NRC existing fire protection regulations. The staff will proceed with the rulemaking when the industry concerns are resolved.

Subactivity 2: **Circuit Analysis Resolution Program**
Another activity related to fire protection is the Circuit Analysis Resolution Program. In response to the need to resolve post-fire safe shutdown, fire-induced circuit failure analysis issues, the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) have respectively developed deterministic and risk-informed post-fire safe shutdown methodology documents. These two documents have recently been combined into one document which provides a step-by-step means of deterministically conducting safe shutdown analyses, while it is intended to provide optional risk-informed methods for selected analytical steps. NEI is currently performing fire tests in an attempt to validate its methodology.

NRR Priority: 6.0

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

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.3 (Subactivity 1) 2.0 (Subactivity 2)	0 100
2002	0.4 (Subactivity 1) 2.0 (Subactivity 2)	0 400

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Publish proposed rule	10/2001	TBD	
Final Rule	4/2002	TBD	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

		2001				2002				2003
Task	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1
Develop a voluntary alternative to fire protection regulation 10 CFR 50.48.											

Implementation Activity: **Develop alternative requirements for safeguards that are risk-informed and/or performance-based. (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.*

The staff has underway a comprehensive review of 10 CFR 73.55. The staff intends to include a requirement for power reactor licensees to conduct drills and exercises to evaluate their protective strategy against a simulated design basis threat. The proposed rule requires that licensees' security programs be based on risk-informed target sets of equipment necessary to prevent core damage and/or spent fuel sabotage.

On June 4, 2001, the staff forwarded to the Commission its proposed rule, recommending publication for public comment (SECY-01-0101). The staff also recommended an extension on the current milestone for publication of the final rule, from November 2002 to June 2003, to allow sufficient time to consider lessons learned from the industry-initiated Safeguards Performance Assessment pilot program, which is expected to be completed in fall 2002.

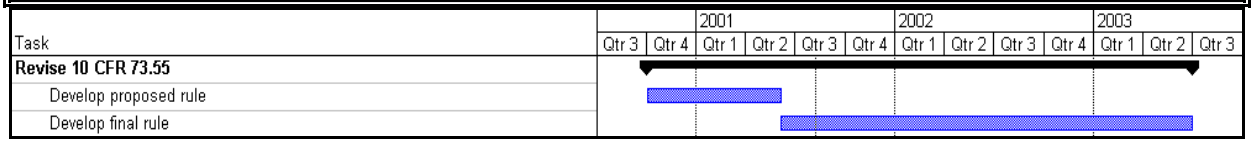
NRR Priority: 8.0

Project Considerations: Not only does the proposed rule permit the application of risk-informed identification of target sets of equipment vital to preventing core damage and/or spent fuel sabotage, it also makes the physical security requirements more performance-based, providing greater flexibility to licensees in designing their physical security program by reducing deterministic requirements and providing performance criteria.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.7	120
2002	2.5	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Proposed rule to Commission	5/2001		6/4/2001
Final rule to Commission	6/2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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.*

The staff is working to develop the technical basis to improve the realism of evaluations of reactor pressure vessel (RPV) integrity to support risk-informed modifications to the regulations associated with RPV integrity. The staff is evaluating the application of advanced fracture mechanics concepts to the revision of the regulatory framework for RPV integrity to provide analysis codes and techniques for evaluating licensee submittals pertaining to RPV integrity, particularly as related to pressurized thermal shock (PTS). The staff is also conducting the research and analyses needed to develop a statistically valid generic flaw density and size distribution for reactor vessel welds and plates for use by the staff and licensees in performing probabilistic fracture evaluations of reactor pressure vessels. In addition, the staff is performing an experimental program and computer analyses to support rulemaking for PTS and guidance for reactor vessel embrittlement. The results of these efforts will be reflected in review guidance documents and in modifications to the regulations addressing issues associated with reactor pressure vessel integrity such as setting operating pressure-temperature limits and LTOP setpoints, and in applying the 10 CFR 50.61 pressurized thermal shock (PTS) screening criteria. Some specific staff activities include: mechanistic and statistical assessments of plant embrittlement data; a report on effects of heat treatment and chemistry unavailability on embrittlement trends; development of the technical bases for revision of RG 1.99; irradiation of high-Cu, high-Ni welds and validation of embrittlement trend curves; an expert elicitation to verify that a generalized flaw size and density distribution can be properly developed for the entire population of U.S. RPVs and to assist in developing a flaw distribution; and calculations to provide technical basis for revising 10 CFR 50.61 (the PTS rule).

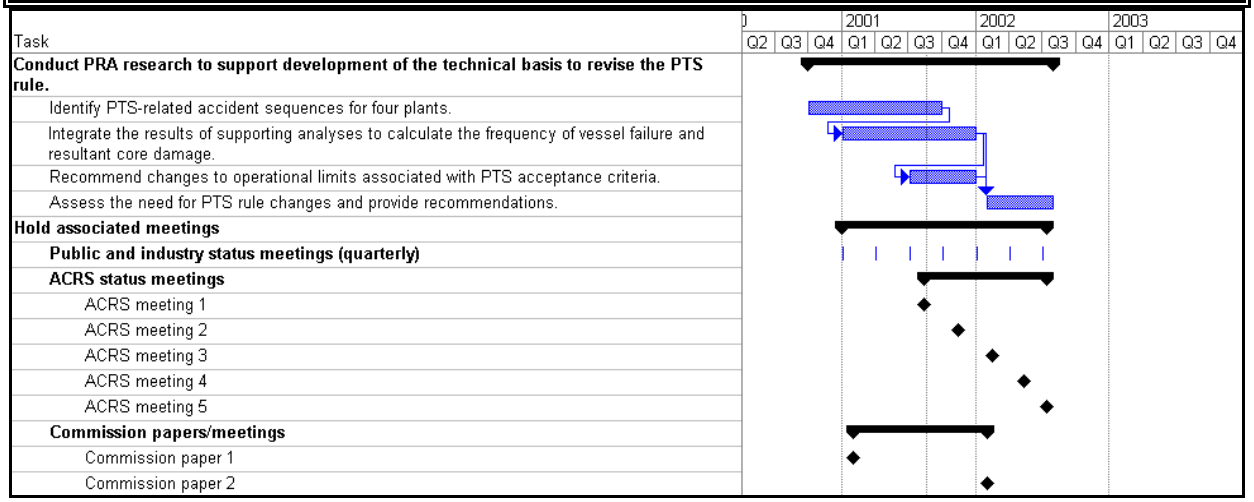
RES Priority: 8.4

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

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	4.0	1000
2002	4.5	1000

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Identify accident sequences significant to PTS for four representative plants	10/2001		
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.	1/2002		
Recommend changes to operational limits associated with PTS acceptance criteria	1/2002		
Assess the need for PTS rule changes and provide recommendations	7/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: PRA Review of Advanced Reactor Applications (NRR & 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 staff has developed a framework that is used to assess possible risk-informed changes to 10 CFR 50. This framework is described in SECY-00-0198. The staff intends to modify this framework for use in the development of the structure of a possible equivalent to Part 50 for advanced reactor designs. In addition, the Nuclear Energy Institute has indicated that it intends to develop a structure for such a new set of requirements. When received, this will be reviewed by the staff.

Details of this staff work have not yet been developed, pending advanced reactor budget decisions. When the resources to be allocated to this activity are defined, the staff will develop more detailed plans and include them in the RIRIP.

NRR Priority: Not yet prioritized
RES Priority: 5.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0	0
2002	TBD	TBD

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

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 tubes in pressurized water reactors is a key consideration in maintaining plant safety during design basis and severe accidents. As design basis accidents, ruptures of tubes can result in offsite radioactive releases that could require emergency response and approach the limits of the 10 CFR 100 siting requirements. As severe accidents, accidents initiated by tube ruptures or involving their failure during accidents 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 tubes found to be deficient are an important element of the industry's safety programs and the staff's regulatory activities.

The staff 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 four parts: probabilistic risk analysis, thermal hydraulics, structural behavior of steam generator tubes and other reactor coolant system components, and offsite consequences. The thermal hydraulic part of this work was initiated in FY 2001, with remaining aspects to be initiated in FY 2002.

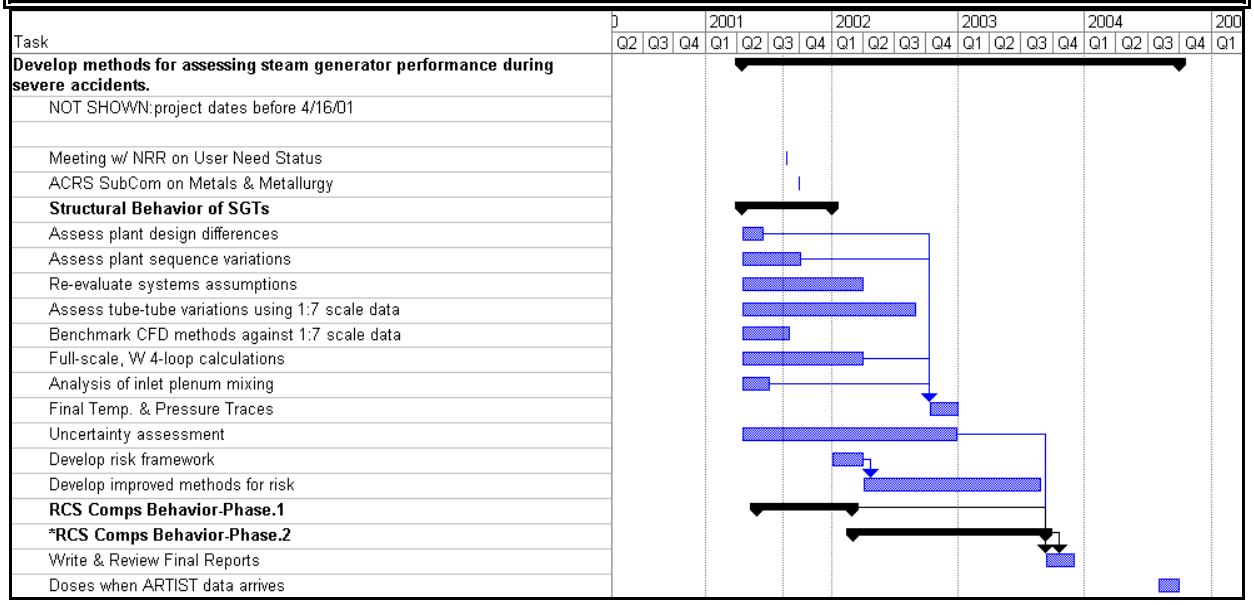
RES Priority: 7.6

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

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001		
2002	TBD	1,375

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Meeting with NRR on user need status	8/01		
ACRS Subcommittee on Metals and Metallurgy	9/01		
Structural behavior of SGTs	12/01		
Full-scale W 4-loop calculations	3/02		
Develop risk framework	3/02		
Develop improved methods for risk	8/03		
RCS components -- Phase I	2/02		
RCS components -- Phase II	9/03		
Final Reports	12/03		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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.*

To help focus staff activities and resources in the reactor safety arena on those items most important to public health and safety, NRR has initiated a three year program whose objective is to create 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 staff's plan for this program includes the following activities.

1. Survey and assess staff, management and Commission perspectives on using risk-informed approaches through focus group meetings and interviews;

2. Analyze past efforts to risk-inform processes in the reactor safety arena to determine lessons learned and best practices;

3. Determine and implement ways in which best practices for using risk-informed approaches for assessing the significance or priority of issues before the staff can be identified and shared among personnel in the reactor safety arena;

4. Develop appropriate information technology instruments that (1) facilitate the sharing of risk knowledge and information and best practices for making assessments of risk significance among personnel in the reactor program; (2) deliver computer-based training on the use of risk-informed approaches and methods.

5. Prepare Office Instructions and other guidance documents as necessary;

6. Communicate the philosophy, policy and practices of risk-informed regulation to staff;

7. Assess program effectiveness using surveys and focus group meetings.

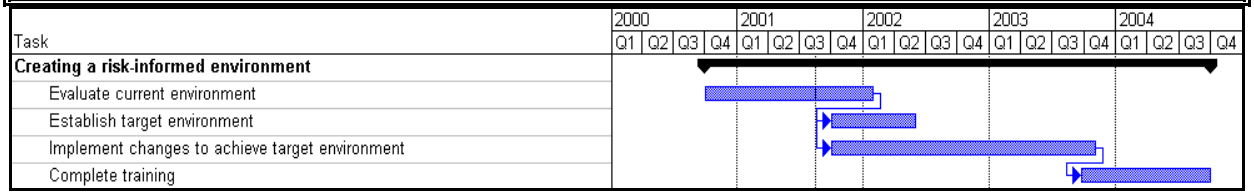
The staff has issued two requests for proposal for contractor assistance in evaluating the current environment for risk-informed approaches and in developing information systems to support the use of risk-informed approaches. The staff has also begun reviewing existing documents that have influenced policy and practices.

NRR Priority: 10.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	2.0	200
2002	4.0	200

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.	12/2001		
Design a target environment for risk-informed regulation acceptable to all stakeholders in the reactor program.	5/2002		
Implement changes to achieve target environment	10/2003		
Assess Effectiveness of Changes	10/2004		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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

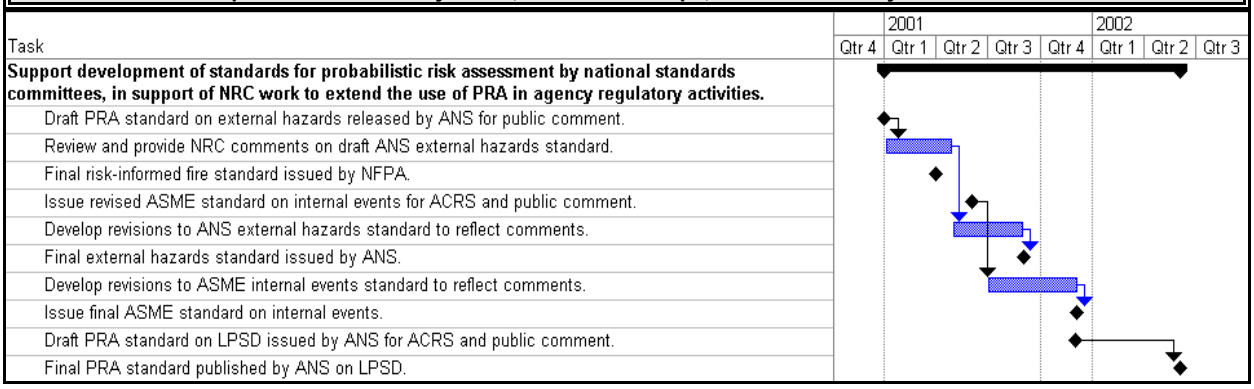
The NRC staff is cooperating with ASME and other organizations to incorporate risk insights into codes and standards applicable to various activities at nuclear power plants. For example, ASME is updating the *Code for Operation and Maintenance of Nuclear Power Plants* and applicable Code Cases to allow the use of risk insights in the inservice testing of pump 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. In addition, the Nuclear Energy Institute is developing guidelines for the implementation of risk-informed alternatives to the requirements in Part 50 of Title 10 to the *Code of Federal Regulations*.

RES Priority: 9.6
NRR Priority: 6.0

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	<0.1 (NRR) 0.1 (RES)	335 (RES)
2002	<0.1 (NRR) 0.1 (RES)	300 (RES)

Selected Major Milestones and Schedules			
Major Milestones[1]	**Original Target Date**	**Revised Date**	**Completion Date**
Final PRA standard issued by ASME	3/2001	12/2001	
Final fire standard issued by NFPA	3/2001		4/2001
Final PRA standards issued by ANS on External Hazards	6/2001	9/2002	
Final PRA standards issued by ANS on Low Power/Shutdown	6/2001	TBD	

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.

Implementation Activity: Develop improved methods for calculating risk in support of risk-informed regulatory decision making (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.*

From the ground-breaking work of the WASH-1400 study and the NUREG-1150 reactor risk studies through the individual plant examinations and present risk studies, tremendous advancements have been made in PRA methods. Consistent with the direction provided in the 1995 PRA policy statement, the NRC is continuing to develop methods needed to better support realistic, risk-informed decision making. Current PRA methods do not adequately address certain key aspects of plant risk, including the effects of quality assurance, human reliability, fire, low power and shutdown operations, degraded SSCs, and digital instrumentation and control failures. Uncertainty concerning the nature and magnitude of the contributions of these aspects to plant risk, particularly as they relate to agency decision making processes and acceptance criteria, will limit progress in risk-informed regulation by requiring conservative decisions to be made to account for large uncertainties. The new methods will complement the methods developed to-date, further reducing uncertainties and improving realism. International cooperation in sharing advanced in methods development are pursued.

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 decision making.

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

- risk contribution of human reliability
- digital system software risk
- quality assurance effects
- MACCS code improvements addressing health effects and land contamination

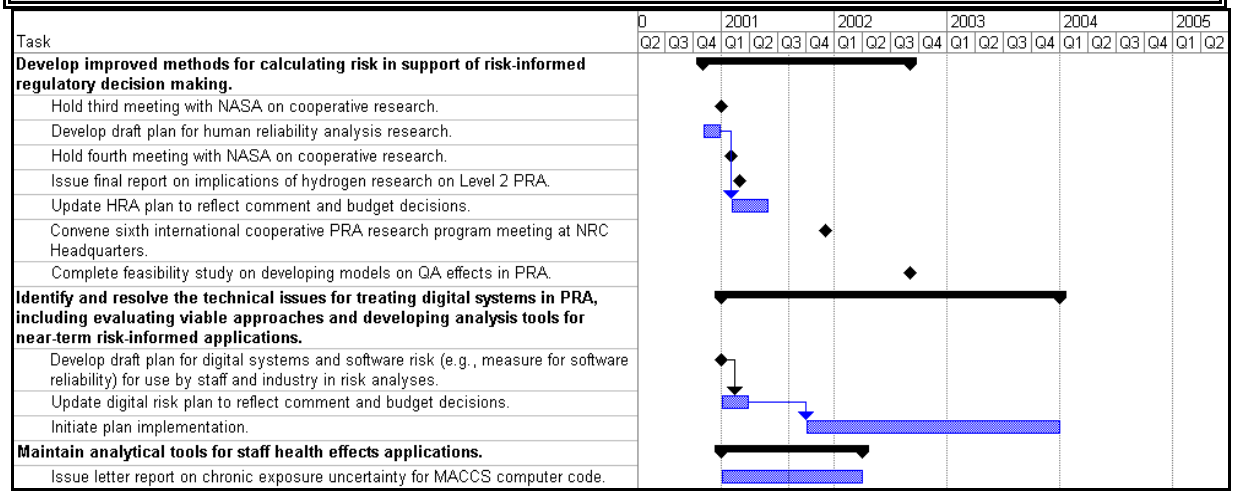
RES Priority: 8.2

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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3	1074
2002	2	400

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Draft plan for HRA research	12/2000		12/2000
Update HRA research plan			5/2001
Draft plan for digital system software risk	12/2000		12/2000
Update digital system software risk plan			5/2001
Complete feasibility study on developing PRA models on QA effects	9/2001	9/2002	
Develop plan to upgrade MACCS on health effects, land contamination	TBD		
Convene sixth international cooperative PRA research program meeting	12/2003		

Implementation Activity Gantt Charts Calendar Year



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.*

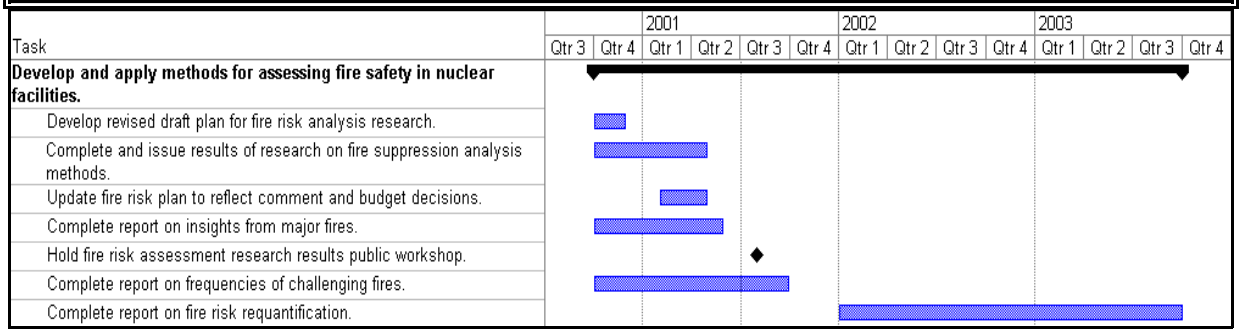
The development of performance-based fire standards and regulations requires a sound understanding of fire and its contribution to power plant risk. Current fire PRA models are not adequate to support credible, risk-informed changes to these standards and regulations. A fire risk program has been developed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

RES Priority: 8.2

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.0	469
2002	2.3	700

Selected Major Milestones and Schedules			
Major Milestones	**Original RIRIP Target Date**	**Revised Date**	**Completion Date**
Revised plan for fire risk	11/2000		5/2001
Issue report on fire suppression analysis methods	12/2000		4/2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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.*

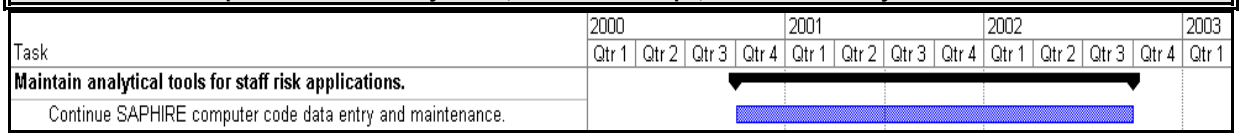
The agency has developed analytical tools that the staff uses in its risk assessments associated with generic safety issues, regulatory backfit reviews, plant operating states, and operational experience. This suite of PRA codes has given the staff the tools it needs to reach risk-informed decisions, independent of licensee analyses. Thus, the staff plans to continue to maintain the SAPHIRE computer code for conducting PRA.

RES Priority: 7.2

Project Considerations: These analytical tools provide support to SPAR and generic issue assessment.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.9	279
2002	1.5	300

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Develop standardized plant analysis risk (SPAR) models for staff risk assessments (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.*

RES is developing SPAR models to permit the NRC staff to independently analyze the risk significance of inspection findings and operational events and/or conditions. The SPAR models being developed include: (1) Level 1 models for full power, low power, and shutdown operations; (2) models for performing large early release frequency (LERF) calculations; (3) detailed models for Level 2 calculations; and (4) analysis tools for external event initiators.

SPAR models will be used by NRR's PRA staff, NRR's inspection staff, and the regional SRAs to determine the risk significance of inspection findings or events so that risk-informed decision scan be made regarding responsive actions. The NRR and RES PRA staffs will use SPAR models to support risk-informed decisions on plant-specific changes to the licensing basis proposed by licensees. NRR's PRA staff will use the SPAR models to perform various studies in support of regulatory decisions as requested by the Commission and other NRR branches. The RES regulatory effectiveness assessment staff and the RES engineering applications staff will use SPAR models in risk evaluations to support the resolution of generic and other safety issues. The RES operating experience and risk analysis staff will use SPAR models to: (1) screen and analyze operating experience data in a systematic manner to identify those events or conditions that are precursors to severe accident sequences as part of the ASP program; (2) assist in the identification of threshold values for risk-based performance indicators (RBPIs) and in the development of an integrated RBPI; (3) analyze operating experience data to determine which risk-significant conditions need more or less regulatory attention, and which regulatory or licensee programs have had an impact on risk and to what degree; and (4) provide rigorous and peer reviewed evaluations of operating experience data to enhance the technical credibility of the NRC's ability to analyze operating experience data independently of licensee's risk assessments.

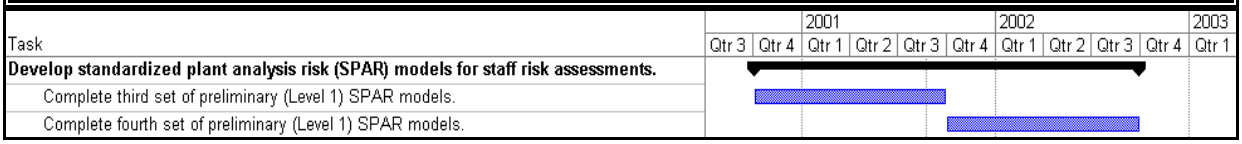
RES Priority: 7

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 SCSS LER database, 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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0	789
2002	2	300

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Complete third set of preliminary (Level 1) SPAR models	9/2001		
Complete fourth set of preliminary (Level 1) SPAR models	9/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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.*

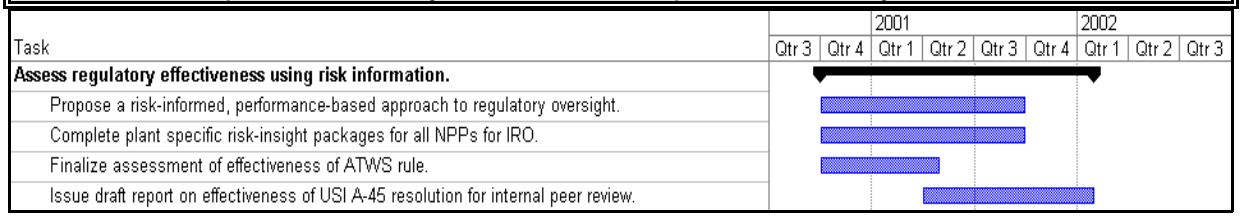
The staff will conduct an integrated evaluation of risk information, inspection findings, operating experience, domestic and international research results, and cost data to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

RES Priority: 9.6

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.8	267
2002	2.3	450

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Evaluate effectiveness of ATWS rule	4/2001		4/2001
Evaluate effectiveness of USI A-45 resolution	9/2001		
Evaluate effectiveness of 10CFR50, App J, Option B	1/2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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.

2.1.1. Background

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.

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 use;
- 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 safety goals 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.

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 two and three.

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 interaction with stakeholders. Such interaction 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) what specific use is the staff expected to make of risk insights and risk assessment in development of regulations and guidance, licensing, inspection, assessment, and enforcement; and (2) what specific use is the licensee expected to make of risk insights and risk assessment in planning and conducting its operations.

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 decision-making. 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.

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 provide technical peer review of the staff's efforts in this area. Also, the Commission approved the reprogramming of six staff full-time equivalents (FTEs) to proceed with this effort.

The Commission indicated that staff should develop appropriate material safety goals, analogous to the NRC reactor safety goal, 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 standard(s) 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.

2.2. NMSS PLAN FOR RISK-INFORMING MATERIALS AND WASTE SAFETY ARENAS

NMSS is following a general, three-phase plan to implementing 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 for 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 two through five 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.

Phase 1 Phase 1 represents NMSS's initial implementation of the SRM's three directives described above in Section 2.1.1.

In August 1999, NMSS staff were identified and reassigned to form the NMSS Risk Task Group. The Risk Task Group currently reports to the Office of the Director, 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, comprised 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.

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 safety goals for nuclear materials and waste applications. The workshop included participation by representatives from NRC, Environmental Protection Agency, Department of Energy, Occupational Safety and Health Administration, Organization of Agreement States, Health Physics Society, Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. A consensus among 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 safety goal parameters and a first draft of safety goals 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 consist of four criteria which address whether a benefit would be realized from modifying a regulatory approach, based on risk information. The four “benefit criteria” stem from the four performance goals identified in the NRC Strategic Plan: maintaining safety, protection of 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 address whether technical feasibility, implementation costs, or other factors would negate the potential benefits of, or significantly hinder, modifying the regulatory approach.

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., safety goals) 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 case study areas were selected to reflect the diversity of NMSS materials and waste regulatory applications and include: 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 will be completed by December 2001. The products of the case studies will be (1) finalization of the screening criteria for identifying NMSS regulatory applications amenable to increased use of risk information, (2) an assessment of how the application of risk information could affect the various NMSS regulatory applications, and (3) the development of draft risk metrics and goals (i.e., safety goals) that would support risk management decision-making in NMSS. The products of the case studies will be used in Phase II to systematically review NMSS materials and waste regulatory applications and determine which applications may be modified to include and reflect risk information.

The primary Phase I activity described in the preceding paragraphs focuses on the development of the general approach that will be used to systematically incorporate risk information into NMSS regulatory applications and support risk management decision-making. Concurrent with this activity, NMSS has begun to incorporate 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.

Also during Phase I, NMSS has begun 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 is developing a three-tier program, reflecting the relative depth and complexity of the course content. 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, administrative and technical staff. Tier III courses will 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 will conclude with the completion of the case study activity, the finalization of the screening criteria for identifying regulatory applications, and the development of draft risk metrics and goals. While the current schedule shows completion of these activities in the first half of 2002, NMSS has accelerated its schedule and hopes to complete the activities before the end of 2001. The Phase I activities that are currently in progress are described individually in Section 2.3, which also provides prioritization, resource commitment, schedule, and other project management information and considerations for the individual activities.

All of these activities are managed through the routine NMSS planning, budgeting, and performance management (PBPM) process and are reflected in the NMSS operating plans.

Phase 2 Phase 2 is expected to begin upon finalization of the screening criteria, described above. Phase 2 will focus on the systematic review of NMSS materials and waste regulatory applications, to identify those that would be amenable to an increased consideration of risk insight and information. Specific Phase 2 activities are not yet defined; however, a general approach has been formulated and is described below.

As a starting point, all NMSS materials and waste regulatory applications will be identified and categorized. Regulatory applications include, for example, rulemaking, guidance development, licensing activities, and inspection and enforcement activities. The staff will utilize the existing NMSS operating plans and budget plans where practicable. Next, the staff will apply the screening criteria to the individual regulatory applications, using the results of the case study activity as guidance. This will allow the staff to benefit from the experience gained through application of the draft screening criteria to the various NMSS regulatory activities considered in the case studies. Application of the screening criteria to the NMSS regulatory applications will identify those areas where a risk-informed approach or modification (1) may result in a benefit, in terms of safety, increased public confidence, increased efficiency and effectiveness, or reduced regulatory burden; and (2) would not be prohibited by technical feasibility, cost effectiveness, or other considerations.

Based on management, policy, or other considerations, staff will not consider certain regulatory areas in the initial screening. Examples would be the regulatory applications associated with 10 CFR Parts 35, 63, and 70. These regulatory applications have been recently revised to be risk-informed and will not be revisited in the initial screening. Additionally, certain regulatory applications may be identified through mechanisms other than the screening process. Such mechanisms include operating experience, Commission direction, stakeholder suggestion, and staff initiatives.

The product of the screening activity is expected to be a set of regulatory activities considered amenable to being risk-informed and a complementary set of activities not considered to be amenable. Staff will provide the supporting justification for the two sets of activities by documenting the application of the screening criteria.

Staff will review and bin the set of regulatory applications considered amenable to being risk-informed, where binning similar or related applications would facilitate the introduction of risk insights and information into the applications. The applications will then be prioritized through the normal PBPM prioritization process. For those activities identified for modification in the near-term, staff will define the scope and project management characteristics (e.g., resource requirements, schedule and milestones, products). Staff will inform the Commission of progress during Phase 2 and will inform the Commission of the results prior to beginning Phase 3.

Phase 3 Phase 3 involves the actual modification of the regulatory applications. Referring to the five-step implementation process described in SECY-99-100, Phase 3 corresponds to steps two through five, described in Section 2.1.1.

Prioritization of Materials and Waste Safety 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(s) is listed under each implementation activity. The prioritization processes followed by NMSS, NRR, and RES management, although not the same, 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.

2.3. 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:

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 (Mallinckrodt Lessons-Learned Review)

MS-MS1-1 Revise Fuel Cycle Oversight Program

MS-MS1-2 Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs

MS-MS2-1 Materials Licensing Guidance Consolidation and Revision

MS-MS2-2 Risk-informed, Performance-based Temporary Instruction for the Nuclear Medicine Program

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)

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-RB1-1 Package Performance Study (Scoping)

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 (currently ongoing)

- 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 safety goals
- Finalize screening criteria
- Develop draft risk metrics and goals (safety goals)
- Continue with specific ongoing risk-informed initiatives and activities
- Develop risk training program for NMSS management and staff
- Report to Commission

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
- Report to Commission

Phase 3

- Implement the risk-informed initiatives identified through Phase 2

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 SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the NRC staff proposed a framework for risk-informed regulation in NMSS. In an SRM dated June 28, 1999, the Commission approved the staff's proposal. As a first step toward developing a framework, the staff proposed establishing a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information. Based on stakeholder input, the NMSS staff decided to pursue case studies with the following purposes: 1) to illustrate what has been done and what could be done in NMSS to alter the regulatory approach in a risk-informed manner; and 2) to establish a framework for using a risk-informed approach in NMSS by testing the draft screening criteria and determining the feasibility of safety goals.

Each case study is of limited scope, but collectively, the case studies cover a broad spectrum of NMSS regulatory applications. A case study plan was developed by the NMSS staff and the NMSS Risk Steering Group. The case studies were selected in representative areas expected to help establish a framework, as well as areas that would help to set the groundwork for establishing safety goals. The staff and its contractor began working on the case studies in October 2000 and are working on the case studies concurrently. When completed, the staff will present the results of the spectrum of case studies to the Commission.

NMSS Priority: Medium

Project Considerations: The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts (ADAMS Accession #ML003780611). Additionally, the case-study approach involves numerous public workshops to solicit stakeholder input, in an enhanced participatory process.

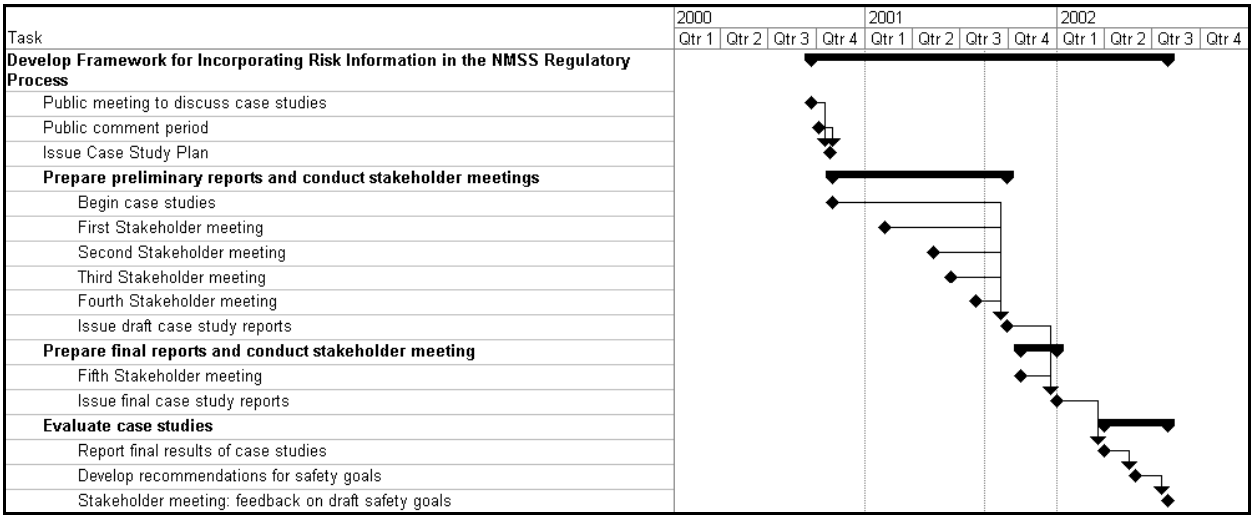
This activity is inter-related with other agency efforts. While the case studies are being conducted concurrently with other ongoing NMSS initiatives and activities to increase the use of risk information in NMSS, the RTG is coordinating with other NMSS staff when an ongoing regulatory activity relates to one of the case studies. Also, in FY02 RES will provide support to the NMSS RTG to integrate the results of the case studies, finalize the draft screening criteria, develop implementation guidance, develop draft safety goals, and review materials and waste regulatory programs for those amenable to increased use of risk information.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	5 (NMSS) 0 (RES)	449 (NMSS) 0 (RES)
2002	3.5 (NMSS) 2.1 (RES)	300 (NMSS) 400 (RES)

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as developing the NMSS risk training program (MS-EER1-2) and providing direct support to NMSS divisions for risk-related activities.

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		
Report final results of case studies	March 2002		
Stakeholder meeting: feedback on draft safety goals	July 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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 is working 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. Tier I training provides a general perspective of risk, risk assessment, and risk management relative to NMSS activities and is intended for NMSS managers and administrative staff. Tier II goes into greater detail than the Tier I training and is intended for NMSS technical staff.

The pilot session of the Tier II course was held September 11-14, 2000. Feedback from the pilot session was used to create a final version of the course (P-400), which was implemented in December 2000. Sessions are being offered through FY2001. The Tier I courses for technical managers (P-401) and administrative staff (P-402) were developed from the P-400 course. The Tier I courses were offered in FY2001.

The staff has begun to develop Tier III training courses for NMSS. The staff completed a "needs assessment" and began to offer specific Tier III training courses in FY01, such as quantitative frequency analysis and layer of protection analysis for FCSS and review of management measures for Part 70. The staff intends to offer user training in the Byproduct Materials Study Database underlying NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Materials System."

NMSS Priority: Medium

Project Considerations: 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.

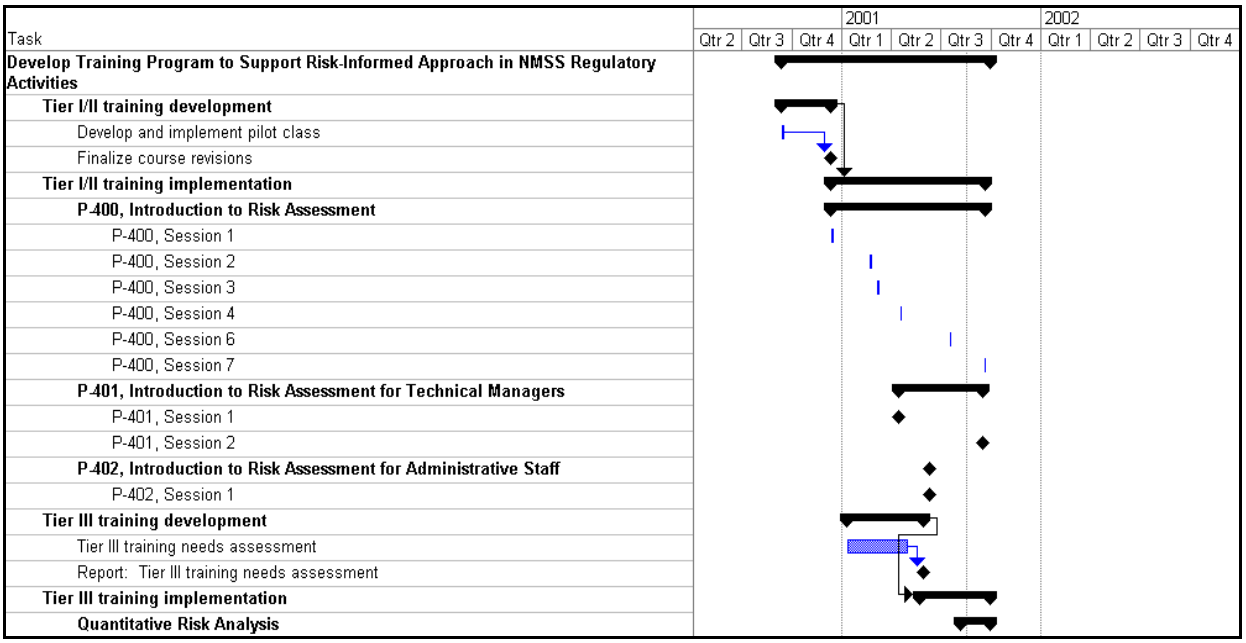
NMSS has developed a communication plan on risk-informing materials and waste regulations (ADAMS Accession #ML003780611). The plan addresses communication with internal stakeholders and the development of the NMSS risk training program.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.75	51
2002	0.5	65

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as the NMSS RTG case-study activity (MS-EER1-1) and providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Begin implementation of Tier II training (P-400)			December 2000
Begin implementation of Tier I training (P-401 and P-402)			April 2001
Complete Tier III training needs assessment			May 2001
Begin implementation of selected Tier III training			May 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Multi-phase Review of the Byproduct Materials Program (Mallinckrodt Lessons-Learned Review)

(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. NMSS 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 recent 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 is reviewing the overall materials program and will recommend necessary changes. The recommendations may include regulatory changes, revisions to the existing licensing and inspection program, and changes to the enforcement policy. Both task groups have used the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

NMSS Priority: High

Project Considerations: Phase II is recommending changes that may call for development of hardware and software for mobile offices. Database development is under consideration, as are inspection priorities and intervals, and an e-commerce approach for simple license applications. A database user's guide and training would be developed and available to staff in FY 2002. Phase II is considering recommendations to address IT issues that impact business processes in the Regions. As NMSS processes are streamlined for efficiency and effectiveness, internal and external customers must receive information to allow them to cooperate with new ways of conducting business.

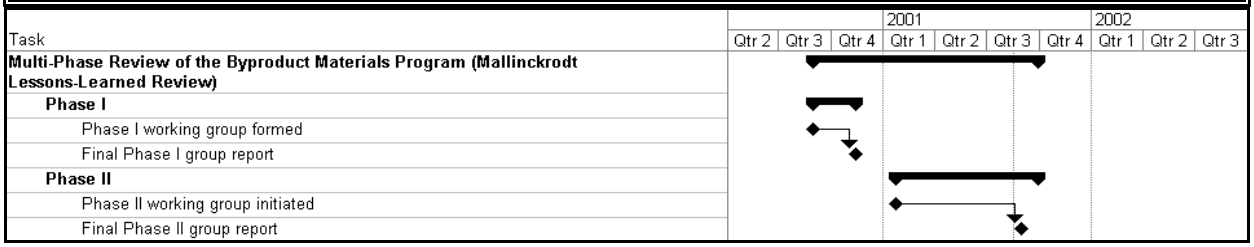
Phase II Task Group includes members from each of the NRC Regions, NMSS, the Office of State and Tribal Programs, and the Office of Nuclear Regulatory Research. These members are receiving information from within NRC and from other federal agencies for benchmarking purposes and are cognizant of developments in the National Materials Program and Event Reporting Task Group.

NMSS has developed a communication plan for the nuclear materials inspection program (ADAMS Accession #ML003758766), which is related to this activity.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	4.0	0.0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Phase I working group formed			August 2000
Final Phase I group report			November 2000
Phase II working group initiated			January 2001
Final Phase II group report			August 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Revise Fuel Cycle Oversight Program

(Lead Organization: NMSS/FCSS)

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)*

NMSS is establishing the framework for making the fuel cycle oversight program more risk-informed and performance-based. Since beginning the initiative in May 1999, NRC staff has conducted nine public meetings to develop revisions to the oversight program, including cornerstones of safety and safeguards. At the most recent meeting (May 2001), stakeholders and NRC staff discussed the role that licensee Problem Identification, Resolution, and Corrective Action Programs will play in the revised oversight process. The revised oversight program will include risk-informed inspections, evaluation of the risk significance of facility events and inspection findings, more scrutable and predictable enforcement and assessment of licensee performance, and enhanced communications with stakeholders. The revised oversight program will build on the risk-informed regulations associated with the new Part 70 rulemaking and will focus on the results of licensees' ISAs. Currently, the NRC is conducting local public meetings in the vicinity of fuel cycle facilities to provide an overview of the changes being made to the NRC's oversight process and to inform local stakeholders how they can participate in the revision process.

NMSS Priority: Medium

Project Considerations: This activity is dependent on other initiatives, including the implementation of the recent revisions to Part 70, lessons learned from NRR's implementation of the Reactor Oversight Process, and lessons learned from the activities of NMSS's Risk Task Group.

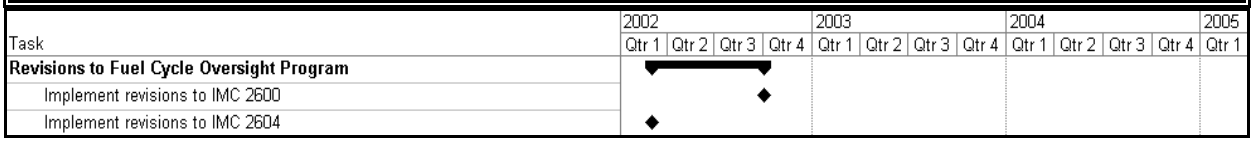
Some training will be needed to familiarize staff and management on process changes.

Also, NMSS has developed a communication plan for the revised fuel cycle facility oversight process (ADAMS Accession #ML003758749).

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	2.0	38
2002	1.5	0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Implement revisions to IMC 2600	October 2001	October 2002	
Implement revisions to IMC 2604	October 2001	March 2002	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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 staff proposes to use a risk-informed approach in the Modified Rulemaking Plan, "Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs". The plan will amend certain sections in 10 CFR Part 72 dealing with seismic siting and design criteria for dry cask independent spent fuel storage installations (ISFSIs). The staff proposes to lower the design earthquake to a level that is commensurate with the lower risk associated with an ISFSI facility.

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 PRA.

This activity is related to an ongoing RES activity, Dry Cask Storage Probabilistic Risk Assessment, that was requested by the SFPO (see activity WS-MS1-1). The RES effort involves a pilot probabilistic risk analysis (PRA) for a dry cask storage system and is expected to provide additional quantitative support for the design earthquake level proposed in the rulemaking. Note that the revised milestone dates reflect the revised schedule proposed in the modified rulemaking plan.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322), which explicitly addresses spent fuel storage and ISFSIs.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	1.0	139
2002	2.8	187

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Proposed rule to EDO	7 months after approval of rulemaking plan	2 months after approval of rulemaking plan	
Final rule to EDO	7 months following end of public comment period	4.5 months following end of public comment period	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

		2001				2002				2003		
Task	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3
Revise Part 72: Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs				◆								

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. (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 completed the first phase of licensing guidance consolidation with the final publication of the following volumes of "Consolidated Guidance about Materials Licenses" (NUREG-1556).

The individual volumes of NUREG-1556 will be reviewed and revised, if needed, following the issuance of the Phase II report from the Multi-phase Review of the Byproduct Materials Program activity. (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 the first to be scheduled for review/revision following the issuance of the Phase II report:

Vol. 1 Program-Specific Guidance About Portable Gauge Licenses
Vol. 2 Program-Specific Guidance About Radiography Licenses
Vol. 3 Applications for Sealed Source and Device Evaluation and Registration
Vol. 4 Program-Specific Guidance About Fixed Gauge Licenses
Vol. 5 Program-Specific Guidance about Self-Shielded Irradiators
Vol. 8 Program-Specific Guidance about Exempt Distribution Licenses

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.

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.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.5	150
2002	1.0	200

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Pending issuance of the Phase II report.	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
				2001				2002				2003
Task	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1
Materials Licensing Guidance Consolidation and Revision						◆						

Implementation Activity: Risk-informed, Performance-based Temporary Instruction for the Nuclear Medicine Program

(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)*

SECY-00-001 and the associated SRM were issued on the staff's proposed medical pilot program (nuclear medicine program) to streamline inspection and enforcement of materials licensees. The approach assesses a licensee's performance relative to desired outcomes. A risk-informed, performance-based Temporary Instruction (TI) for the medical pilot program uses a focus element approach to assess a licensee's performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections.

NMSS Priority: High

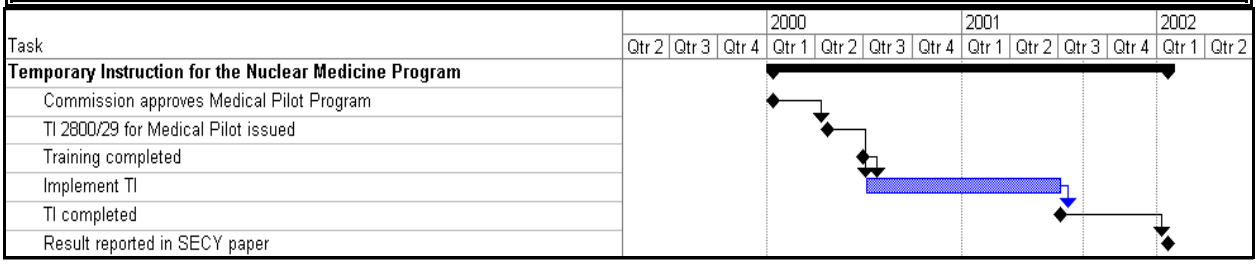
Project Considerations: Lessons learned from the medical pilot program will be incorporated with the implementation of the revised Part 35 and recommendations from Phase II of the Multi-phase Review of the Byproduct Materials Program activity.

Regional inspectors have been trained on the TI.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	See note[2]	0.0
2002	See note[3]	0.0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
SRM for SECY-01-001, approving Medical Pilot Program			January 2000
TI 2800/29 for Medical Pilot Program			April 2000
Training completed and TI Implemented			June 2000
TI completed			June 2001
Results of pilot program reported to Commission	January 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



[2]Inspections are conducted in accordance with regular inspection frequency and are part of regional budgeted inspection efforts in FY01.

[3]No special budget item to develop commission paper in FY02.

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) that amends 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.

FCSS staff, along with the RTG, are currently developing a Standard Review Plan to implement the requirements of Subpart H. This guidance document, which is near completion, 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.

NMSS Priority: Medium

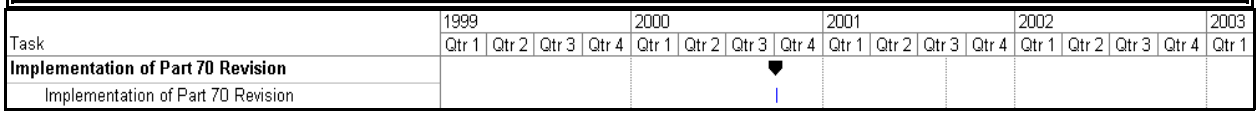
Project Considerations: The NMSS Risk Task Group (RTG) conducted two training sessions to guide ISA reviewers through Subpart H of 10 CFR Part 70 and Appendix A of Chapter 3 of the SRP which provides a method for the licensees for conducting ISAs and preparing ISA Summaries. No additional classroom training is anticipated in FY 2002. Continued guidance from the RTG, as the initial ISA reviews are conducted, will prove to be beneficial. This activity is related to enhancing external communications in that several stakeholders are involved, including NEI and the licensees.

There have been no significant relationships with and dependencies on activities external to NMSS. However, in developing guidance for 70.72 "Facility changes and change process," coordination with individuals in NRR and the SFPO who were involved in developing guidance on 10 CFR 50.59 and 10 CFR Part 72.48 may prove to be beneficial.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	2.0	0.0
2002	2.5	0.0

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Schedule and milestones under development			

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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 is currently preparing a draft rulemaking plan to amend the regulation using a risk-informed approach.

NMSS Priority: Medium

Project Considerations:

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.7	0.0
2002	1.0 (dependent on approval of rulemaking)	0.0

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

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year

	2000				2001				2002				2003
Task	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1
Revise Part 36: Panoramic Irradiators (PRM-36-01)													
Rulemaking plan to EDO							◆						

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)

The staff is currently using the risk information in NUREG/CR-6642 in its analysis of the "Petition for Rulemaking," PRM-34-05, which 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. With the assistance of a contractor, the staff assessed the risk of using associated equipment that has not been evaluated for design and performance criteria as components in gamma radiography systems. The staff is reviewing the assessment and, if appropriate, will use the findings to prepare a rulemaking plan for Commission consideration.

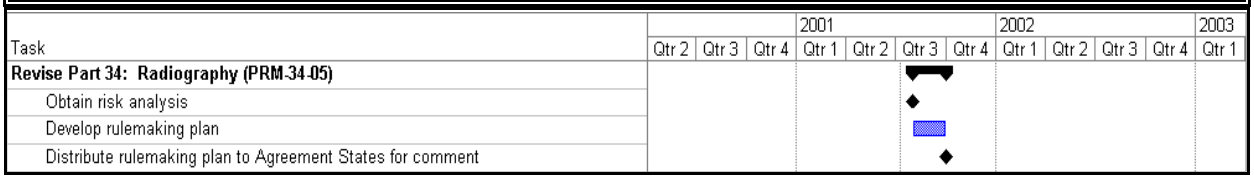
NMSS Priority: High

Project Considerations: The staff is working with the ANSI N43.9 Committee on the review and revision of design and performance criteria for the consensus standard for gamma radiography equipment. If ANSI N43.9 does not publish a standard that addresses associated equipment apart from a gamma radiography system, then the staff will consider development of a government-unique standard. A communication plan will be developed to inform internal and external customers.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.3	0.0
2002	0.3	80

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Obtain risk analysis	July 2001		July 2001
Develop rulemaking plan and distribute a draft to Agreement States for comment	September 2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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. (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)*

The staff has initiated a spent fuel dry storage cask probabilistic risk assessment (PRA). This project will develop a method for performing a PRA for spent fuel dry cask storage systems and perform the first NRC dry cask storage system “pilot” PRA. The results of the project would then lead to recommendations as to whether or not it would be cost-beneficial for PRAs to be performed for every cask design and site. Risk insights from the study will be used to support the staff's decision-making activities and implementing programs involving dry cask storage.

NMSS Priority: High
RES Priority: 7.2

Project Considerations: 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.

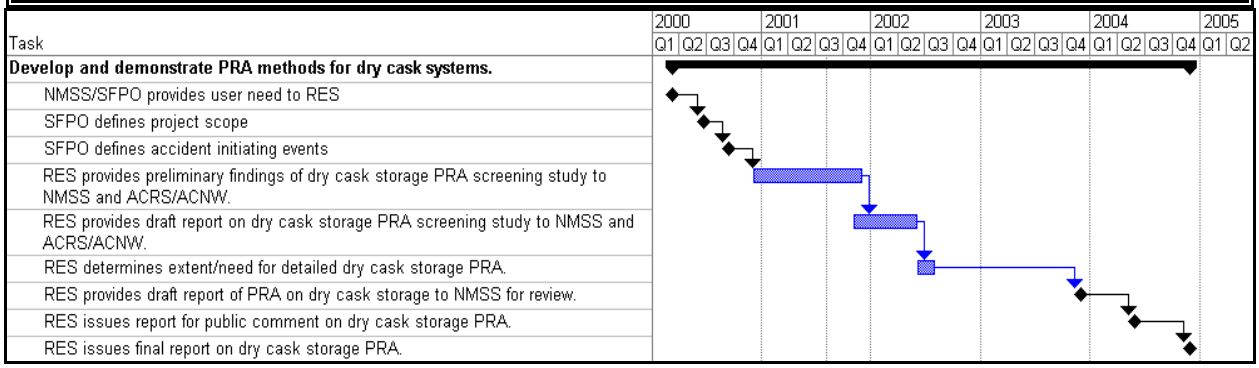
SFPO staff are taking PRA training presently offered through the TTC. Additionally, selected technical staff are being trained on the specific codes employed in conducting this activity.

NMSS has developed a communication plan for the high level waste program (ADAMS Accession #ML003753322) which explicitly addresses dry cask storage systems.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.6 (NMSS) 1.0 (RES)`	0 (NMSS) 100 (RES)
2002	1.8 (NMSS) 3.4 (RES)	0 (NMSS) 1100 (RES)

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue user need request			March 2000
Define project scope and initiate PRA			June 2000
Conduct briefing on preliminary integrated risk results	11/2001		
Complete screening PRA and issue a draft report on integrated risk results	4/2002		
Finalize screening PRA and issue report	TBD		
Initiate detailed risk calculations for significant accident scenarios	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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. (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 April 2001 staff identified several actions being undertaken by the Regions to improve the efficiency of inspections at sites undergoing decommissioning. These actions include focusing resources at sites actively being decommissioned, linking inspections to licensee's on-site activities (to allow inspectors to make side-by-side observations and measurements during licensee's surveys) and limiting the scope and depth of inspections to examining key decommissioning activities. Focusing inspections to improve efficiency should also result in a more risk-oriented inspection approach, as inspections will focus on those decommissioning activities that could increase risks to workers, the public or the environment.

In August 2001, the NMSS Division of Waste Management will complete an evaluation of a decommissioning pilot program which tested a performance-based decommissioning review process. The pilot program focused on residual contamination goals and allowed participants to decommission their sites without obtaining approved decommissioning plans. The pilot program started with five participants; two site were dropped prior to completion. Participants that completed the program indicated that their experiences were positive and that the revised process resulted in schedule and cost savings. Staff is currently evaluating participant information and developing recommendations for the Commission.

NMSS is currently reviewing 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).

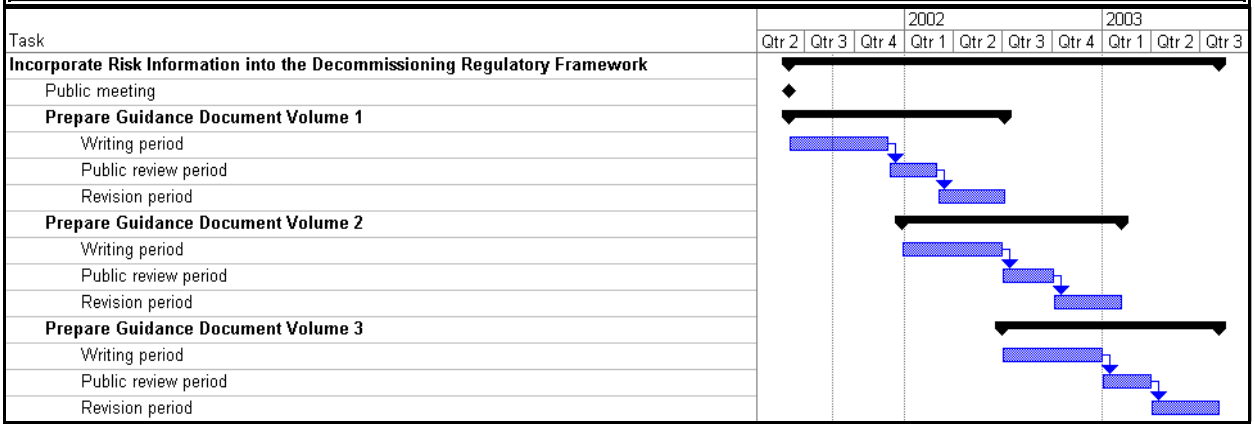
NMSS Priority: Low

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 Volume 1 writing team is considered to be a critical path activity.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	3.9	0
2002	2.7	65

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
Convene the Volume 1 writing team	June 2001		June 2001
Volume 1 (draft) released for public comment	November 2001		
Volume 1(final) released	July 2002		
Convene the Volume 2 writing team	January 2002		
Volume 2 (draft) released for public comment	June 2002		
Volume 2(final) released	January 2003		
Convene the Volume 3 writing team	July 2002		
Volume 3 (draft) released for public comment	December 2002		
Volume 3(final) released	July 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



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 March 2000, the staff completed and provided a final Yucca Mountain risk-informed, performance-based rule making package (Part 63) to the Commission. This version of the final Part 63 focused on implementing a risk-informed approach based on expectations of what the final Environmental Protection Agency (EPA) high-level waste standards (40 CFR 197) would contain.

In September 2000, Revision 1 of the Yucca Mountain Review Plan was completed and provided to the Commission. The review plan provides guidance to staff on implementing the risk-informed, performance-based regulations of 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 final EPA standards (Part 197) were released in June 2001, and the staff has revised the March 2000 version of Part 63 accordingly. The staff is in the process of revising the Yucca Mountain Review Plan to incorporate the final Part 197 requirements in a risk-informed, performance-based manner.

The staff is preparing preliminary sufficiency comments on the Department of Energy's Site Recommendation proposal based upon the risk-informed framework of the review plan. These comments will be provided to the Commission and will be provided to the DOE as part of their Site Recommendation. The comments should enhance any potential DOE application for a license for a repository.

NMSS Priority: High

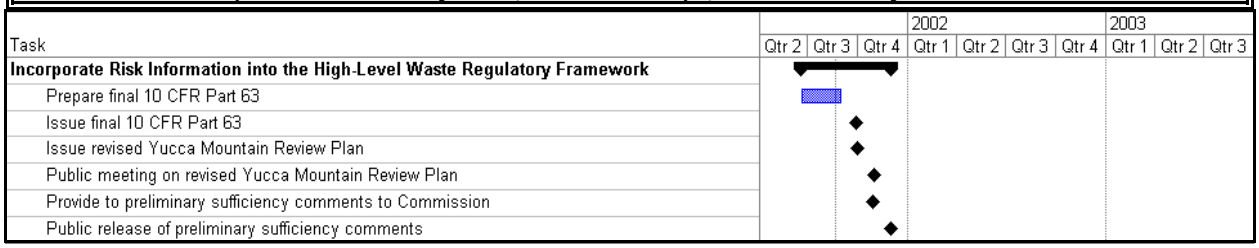
Project Considerations: Completion of the review plan will enhance the ability of the staff and a potential license applicant to understand and comply with NRC's Part 63 requirements. The review plan will also be used to explain to external stakeholders how the NRC would review a potential license application.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

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

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	10.9	2,078
2002	2.9	875

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
Issue Final 10 CFR 63	September 2001		
Issue Yucca Mountain Review Plan	September 2001		
Public meetings on Yucca Mountain Review Plan	October 2001		
Provide staff preliminary sufficiency comments to Commission	October 2001		
Public release of preliminary sufficiency comments	November 2001		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year



Implementation Activity: Package Performance Study (Scoping)

(Lead Organizations: NMSS/SFPO and RES)

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

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

The NRC's transportation risk studies provide a technical basis for determining that current regulations are sufficient to prevent releases of radioactive material during transport. The Package Performance Study is the fourth transportation risk study undertaken by the NRC and provides a process for public involvement in the decision making process for further studies.

The Package Performance Study focuses on spent nuclear fuel cask responses to severe transportation accidents. The objective of the Package Performance Study is to address remaining spent fuel transportation issues from two previous transportation risk studies: the Modal Study (NUREG/CR-4829, February 1987) and the "Reexamination of Spent Fuel Transportation Risk Estimates" (NUREG/CR-6672, February 2000). The Package Performance Study is using a public-participation approach to solicit public and stakeholder interests in developing the study's scope and parameters for review. Further, whereas the preceding studies have all been analytical in nature, the "Package Performance Study" will consider the use of physical testing to address issues, where appropriate. Risk insights obtained using current analysis techniques, physical testing, and through interaction with stakeholders and the public will support NRC's ongoing efforts to assure that its regulatory actions are risk-informed and effective. The staff is using an enhanced public participation process to both design and eventually conduct the "Package Performance Study."

The first phase of the Package Performance Study was a scoping study of possible follow-on work to the previous studies. Four public meetings (two workshops and two seminars) were held in 1999 to solicit input and identify issues. An issues report documenting the results of the scoping study was issued in June 2000. Four public meetings (two workshops and two seminars) were held in 2000 to present the issues report. Ongoing public interactions throughout this project will help ensure that public concerns are effectively identified and understood and that the study design considers these issues.

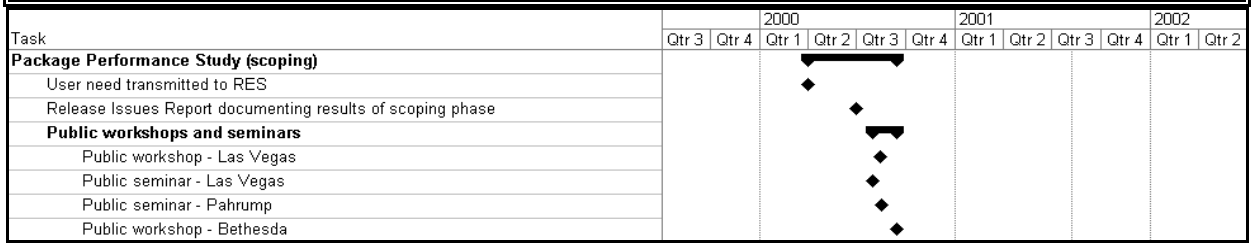
NMSS Priority: High
RES Priority: 8.2

Project Considerations: This activity requires technical assistance from CNWRA and national laboratories and development of analytical and calculational methods. RES is supporting this effort by conducting the research required to validate the ability of computer codes to model extreme loading conditions as may occur in “beyond design basis” accidents.

SFPO staff are taking PRA training presently offered through the TTC. Additionally, selected technical SFPO staff are being trained on the specific codes employed in conducting this activity.

Numerous public meetings have been held to solicit input on issues and design of study. Interactions with public through meetings and a web site will continue. Also, NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322), which explicitly addresses transportation of spent fuel.

Resources Budgeted		
Fiscal Year	**Staff Resources (FTE)**	**Fiscal Resources (K$)**
2001	0.6 (NMSS) <0.1 (RES)	160 (NMSS) 575 (RES)
2002	0.5 (NMSS) 0.5 (RES)	200 (NMSS) 850 (RES)

Selected Major Milestones and Schedules			
Major Milestones	**Original Target Date**	**Revised Date**	**Completion Date**
User need transmitted to RES			March 2000
Issues report released			June 2000
Public seminars and workshops			August - September 2000
SFPO/RES consulting with DOT, DOE and others on need for testing	ongoing		
Develop for test plan and implementation	ongoing		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year