# Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
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Attachment 2

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

| | |
|---|---|
| GAO | General Accounting Office (now Government Accountability Office) |
| GDC | general design criterion/criteria |
| GEM | graphical evaluation module |
| GL | generic letter |
| GQA | graded quality assurance |
| | |
| HERA | Human Event Repository and Analysis |
| HRA | human reliability analysis |
| HLW | high level waste |
| | |
| IDCCS | Integrated Data Collection and Coding System |
| IMC | Inspection Manual Chapter |
| IMNS | Division of Industrial and Medical Nuclear Safety (NMSS/IMNS) |
| INPO | Institute of Nuclear Power Operations |
| IPEEE | individual plant examination - external events |
| IPE | individual plant examination |
| ISFSI | independent spent fuel storage installation |
| ISA | integrated safety analysis |
| ISI | inservice inspection |
| IST | inservice testing |
| | |
| LCO | limiting conditions for operation |
| LER | Licensee Event Report |
| LERF | large early release frequency |
| LOCA | loss of coolant accident |
| LOOP | loss of offsite power |
| LPSD | low power/shut down |
| LRS | low-risk significant |
| LT | leadership team |
| LTR | License termination rule |
| | |
| MACCS | MELCOR accident consequence code system |
| MOR | Monthly Operating Report |
| MSLB | main steam line break |
| MSPI | Mitigating systems Performance Index |
| | |
| NEI | Nuclear Energy Institute |
| NFPA | National Fire Protection Association |
| NMSS | NRC Office of Nuclear Material Safety and Safeguards |
| NOED | notice of enforcement discretion |
| NRC | Nuclear Regulatory Commission |
| NRS | non-risk significant |
| NRR | NRC Office of Nuclear Reactor Regulation |

| | |
|---|---|
| OAS | Organization of Agreement States |
| OCFO | NRC Office of the Chief Financial Officer |
| OEDO | NRC Office of the Executive Director for Operations |
| OM | operation and maintenance |
| OSTP | NRC Office of State and Tribal Programs |
| PA | performance assessment |
| PBPM | planning, budgeting, and performance management |
| PRA | probabilistic risk assessment |
| PRASC | PRA steering committee |
| PRM | petition for rulemaking |
| PTS | pressurized thermal shock |
| PWR | pressurized-water reactor |
| QA | quality assurance |
| RADS | reliability and availability data system |
| RASP | Risk Assessment Standardization Project |
| RBI | risk-based performance indicators |
| RES | NRC Office of Nuclear Regulatory Research |
| RG | regulatory guide |
| RI | risk-informed |
| RIE | risk-informed environment |
| RILP | risk-informed licensing panel |
| RIPB | risk-informed performance-based |
| RIRIP | risk-informed regulation implementation plan |
| RIS | regulatory issue summary |
| ROP | reactor oversight process |
| RPV | reactor pressure vessel |
| RTG | Risk Task Group (NMSS) |

| | |
|---|---|
| SAPHIRE | Systems Analysis Program for Hands-on Integrated Reliability Evaluation |
| SBO | station blackout |
| SCSS | sequence coding and search system |
| SDP | significance determination process |
| SFPO | Spent Fuel Project Office (NMSS) |
| SG | steam generator |
| SGTAP | steam generator task action plan |
| SNM | special nuclear material |
| SPAR | standardized plant analysis risk |
| 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 |
| TS | technical specification |
| TSTF | Technical Specification Task Force |
| TTC | NRC Technical Training Center |
| | |
| UAI | (system) unavailability index |
| URI | (system) unreliability index |
| USI | Unresolved Safety Issue |
| | |
| WOG | Westinghouse Owners Group |

# FOREWORD

The 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 plant licensees.

The Commission also said:

> Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decisionmaking.

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

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

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

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

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

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

Organization of the RIRIP

The RIRIP consists of two parts. Part 1 provides a general discussion of risk-informed regulation applicable to three of the primary strategic arenas. Part 1 first discusses the relevance of the RIRIP to the Agency's Strategic plan, and provides general guidelines for identifying "candidate" requirements, practices, and process that may be amenable to, and benefit from, an increased use of risk insights. Part 1 then provides a discussion of factors to consider in risk-informing the Agency's activities, including defense-in-depth, safety margins, the ALARA principle, and safety goals. Finally, Part 1 provides a general discussion of communications plans and training programs.

Part 2 of the plan describes the staff's activities for risk-informed regulation that are specific to the strategic arenas and is based on the Commission's strategic plan for FY 00-05, with chapters on the Nuclear Reactor Safety arena, Nuclear Materials Safety arena, and Nuclear Waste Safety arena. A new strategic plan for FY 04-09 was recently approved and Part 2 will be revised in the next RIRIP update to align with the new goals and strategies identified in the new plan. Each chapter is organized around the current strategic plan strategies relevant to risk-informed regulation in that arena. The implementation activities for each strategy are described, significant milestones are listed, and milestones schedules are noted. Progress in completing established milestones is also discussed.

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

# PART 1. RISK-INFORMED REGULATION

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

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

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

## 1. Relevance to the Strategic Plan

While the PRA policy statement and other risk-informed regulatory initiatives were being developed, the NRC also developed a strategic plan for accomplishing its mission. The strategic plan for FY 00-05 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).

In August 2004, the Agency issued a revised Strategic Plan for Fiscal Years 2004 to 2009 (FY 04-09). This new plan established five goals, and the associated strategies which the Agency will use to achieve each goal. These goals are Safety, Security, Openness, Effectiveness, and Management. In response to the release of the new Strategic Plan for FY 04-09, the staff is in the process of revising the RIRIP for future updates to make it consistent with the five goals in the FY 04-09 Strategic Plan. In this RIRIP update, each activity also lists the Primary and Secondary Performance Goals and Strategies associated with the FY 04-09 plan. The staff intends to further revise the RIRIP in the next update to be consistent with the FY 04-09 Strategic Plan.

## 2. Guidelines for Selecting "Candidate" Requirements, Practices, and Processes

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

(1) Could a risk-informed regulatory approach help address one or more goals in the Commission's Strategic Plan?

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

(2) Do information (data) and/or 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 consideration 2 is yes, proceed to next consideration; if not, the activity is considered to be screened out.*

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

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

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

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

## 3. Factors To Consider in Risk-Informed Regulation

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

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

Risk-informed requirements must maintain reasonable assurance of adequate protection. A challenge in risk-informed regulation will be to maintain an acceptable level of safety while (1) improving effectiveness, efficiency, and realism in agency decisions, practices, and processes, (2) increasing public confidence in the agency, and (3) reducing unnecessary regulatory burden on licensees.

To establish a consistent approach, the following factors (discussed in the paragraphs below) should be considered in risk-informing an agency requirement or practice:

- Defense-in-Depth
- Safety Margins
- ALARA Principle
- Safety Goals
- Performance-Based Implementation
- Voluntary Alternatives Versus Mandatory Requirements
- Selective Implementation

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Figure 1
Risk-Informed Regulation Implementation Plan
Accession Number ML030310507

- Regulatory Oversight Activities
- Regulatory Analysis

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

Defense-in-Depth

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

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

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

> The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:
>
> - Defense-in-depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and extent of compensatory measures should be related, in part, to the degree of uncertainty.
> - The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity.

- How good each compensatory measure should be is, to a large extent, a value judgement and, thus, a matter of policy.

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

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

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

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

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

  - the need for redundancy, diversity, and independence of systems?
  - the events that need to be considered in the design?
- Do the defense-in-depth considerations in RG 1.174 apply?

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

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

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

Safety Margins

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

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

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

- How should safety margins be employed to account for uncertainty in risk?
  - parameter uncertainty; defense-in-depth (i.e., redundancy, diversity, independence)?
  - incompleteness in risk analysis (e.g., engineering judgment)?
  - model uncertainty (e.g., conservative acceptance criteria)?

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

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

The ALARA Principle

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

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

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

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

Safety Goals

In general, a safety goal is useful to define the desired level of safety. In the Reactor arena, safety goals were established to define “how safe is safe enough” or, in other words, when additional regulation is not warranted. The agency uses these goals as benchmarks for calculated risk measures. The Commission has directed the staff to develop risk guidelines for the Materials and Waste Safety arenas similar to the reactor safety goals, but taking the diversity of NMSS into account.

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

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

Performance-Based Implementation

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

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

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

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

Voluntary Alternatives Versus Mandatory Requirements

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

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

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

Selective Implementation

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

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

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

Regulatory Oversight Activities

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

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

Regulatory Analysis

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

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

As part of the staff's activities, the role of regulatory analysis in the evaluation of risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework. In this regard, in response to Commission concerns about bundling individual

requirements in proposed risk-informed changes to 10 CFR Part 50 (Option 3) and 10 CFR 50.44 (Combustible Gas Control), the staff issued 69 FR 29187 (May 21, 2004).

## 4. Communication Plans

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

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

In addition to these specific communication plans, RES is continuing development of the Risk Communication Project, coordinating with several other offices, which develops guidance to improve the communication of risk insights and information to all NRC stakeholders. Guidelines for External Risk Communication (NUREG/BR-0308) contains practical, how-to guidance for NRC staff and management on NRC-specific communication topics and situations that deal with risk. The Technical Basis for the NRC's Guidelines for External Risk Communication (NUREG/CR-6840) includes suggestions on how NRC staff can use the risk communication principles in the Guidelines for their communications with external stakeholders. This report discusses the development of the Guidelines and includes a comparison of the NRC's needs to the state-of-the-art in risk communication practices.

## 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 has identified, developed, and implemented staff training to ensure that the staff is fully prepared for risk-informed regulation. Training activities are described in further detail in Part 2.

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# 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, which were established by the Strategic Plan for FY 00-05. Part 2 of the RIRIP has two chapters: Chapter 1 addresses the Reactor Safety arena, and Chapter 2 addresses the Nuclear Materials and Waste Safety arenas. (For clarity, the Materials and Waste arenas are presented together since NMSS has primary responsibility for both.) At the beginning of each chapter is a summary describing the general plan for increasing the use of risk insights in regulatory activities.

Each chapter provides individual, detailed discussions of the implementation activities, including project management considerations and more detailed schedule and milestone information. Figure 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 crosscutting activities identified by RES, NRR, and NMSS. For example, the first activity listed is RS-MS1-1, for which seven activities were identified as related (or crosscutting) in some way. Within each activity are critical path milestones that must be accomplished for that activity to be completed. The activity milestones are shown on the schedules (Gantt charts) associated with each of the activity descriptions presented in Chapters 1 and 2 of this part.

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

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

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

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

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-2 Inspection Program
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-5 SPAR Models

### *RS-MS3-1* Reactor Oversight Process Support

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

### *RS-MS3-2* Industry Trends Support

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

### *RS-MS3-3* Reactor Performance Data Collection Program

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

### *RS-MS3-4* Accident Sequence Precursor Program

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

### *RS-MS3-5* SPAR Model Development Program

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

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

- RS-MS3-3 Reactor Performance Data Collection

- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-7 PRA Adequacy Reg Guide

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

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

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

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

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

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

*RS-MS8-6* Fire protection for nuclear power plants

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

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

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

*RS-MS8-8* PRA Review of advanced reactor applications

- RS-MS8-10 Develop structure for new plant licensing
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

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

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

*RS-MS8-10* Advanced Reactor Framework

- RS-MS8-8 PRA Review of advanced reactor applications
- RS-EER1-2 PRA standards and development

*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-MS8-1 Special Treatment Requirements
- RS-MS8-3 Emergency Core Cooling Systems
- RS-MS8-4 Additional Changes to Part 50
- RS-MS8-5 Standard Technical Specifications
- RS-MS8-10 Develop structure for new plant licensing
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

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

- RS-MS3-5 SPAR Models
- RS-MS8-7 PTS Rule Revision
- RS-MS8-8 PRA review of advanced reactor applications
- RS-MS8-9 Steam Generators
- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-7 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

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

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

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

- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-5 SPAR Models
- RS-MS8-8 PRA review of advanced reactor applications
- RS-MS8-9 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-7 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

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

- RS-MS3-5 SPAR Models
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods

- RS-EER1-5 Maintain Analytical Tools
- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-MS1-1 Dry Cask PRA

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

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

### *RS-EER1-9* Phased approach to achieving appropriate PRA quality and completeness

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

## Wastes and Materials Arenas

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

- MS-EER1-4 Develop Risk Guidelines for Materials and Waste Arenas
- RS-EER1-2 PRA Standards Development
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

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

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

### *MS-EER1-5* Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium

- No crosscutting activities identified.

### *MS-EER1-6* Risk-Informed Decisionmaking Guidance Development

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

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

- MS-MS2-1 Materials Licensing Guidance
- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

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

- No crosscutting activities identified.

### *MS-MS2-1* Materials Licensing Guidance Consolidation and Revision

- MS-EER2-1 Review of Byproduct Materials Program

### *MS-MS2-3* Implementation of Part 70 Revision

- No crosscutting activities identified.

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

- No crosscutting activities identified.

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

- No crosscutting activities identified.

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

- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools

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

- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

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

- MS-EER1-6 Risk-Informed Decisionmaking Guidance Development

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Figure 2
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# CHAPTER 1. REACTOR SAFETY ARENA

**Ellis Merschoff, 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 for the Review of Safety Analysis Reports for Nuclear Power Plants" (NUREG-0800) for licensing reactors and some of the regulatory guides supporting NUREG-0800 provided review and evaluation guidance with respect to these probabilistic considerations.

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

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

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

In considering what areas in the Reactor Safety arena to target for greater use of risk information, the NRC staff examined the sources of risk, the existing regulatory processes, and where the best opportunities for improvements were. This led to a focus on reactors operating at power, but also gave consideration to (1) low power and shutdown conditions, (2) reactors

undergoing decommissioning with fuel stored in pools (discussed under the nuclear waste arena), and (3) advanced reactor designs.

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

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

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

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

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

Reactor Safety Arena

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

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

Prioritization of Reactor Safety Arena RIRIP Implementation Activities

In response to the Commission's direction in the January 4, 2001, SRM on the October 2000 version of the RIRIP, the priority rating is listed under each implementation activity. Staff activities are prioritized as they relate to maintaining safety; improving effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence. The scale is from 1 - 15, with 1 being the highest priority. These priorities were determined through the Planning, Budgeting, and Performance Management (PBPM) process. As part of the FY 2006 PBPM process, the program offices developed a common prioritization methodology and used it to produce a prioritized listing of planned activities. The offices continued to use the Common Prioritization Methodology to plan, budget, and implement RIRIP activities. As with other staff activities, changes in priorities of the staff's risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities.

## 1.2. Description of Current Initiatives and Activities

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

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

Reactor Safety Arena

| | |
|---|---|
| RS-MS1-2 | Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant. |
| RS-MS1-3 | Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information |
| RS-MS3-1 | Reactor Oversight Process Support |
| RS-MS3-2 | Industry Trends Support |
| RS-MS3-3 | Reactor Performance Data Collection Program |
| RS-MS3-4 | Accident Sequence Precursor Analysis Program |
| RS-MS3-5 | SPAR Model Development Program |
| RS-MS8-1 | Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method |
| RS-MS8-3 | Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”) |
| RS-MS8-4 | Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50 |
| RS-MS8-5 | Develop risk-informed improvements to the standard technical specifications (STS) |
| RS-MS8-6 | Fire protection for nuclear power plants |
| RS-MS8-7 | Develop the technical basis to revise the PTS rule |
| RS-MS8-8 | Develop the technical basis to support risk-informed review of advanced reactors |
| RS-MS8-9 | Develop methods for assessing steam generator performance during severe accidents |
| RS-MS8-10 | Advanced Reactor Framework |
| RS-EER1-1 | Creating a risk-informed environment |

Reactor Safety Arena

| | |
|---|---|
| RS-EER1-2 | Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees |
| RS-EER1-3 | Develop improved methods for calculating risk in support of risk-informed regulatory decisionmaking |
| RS-EER1-4 | Develop and apply methods for assessing fire safety in nuclear facilities |
| RS-EER1-5 | Develop and maintain analytical tools for staff risk applications |
| RS-EER1-7 | Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications. |
| RS-EER1-8 | Coherence Program for Reactor Safety Arena |
| RS-EER1-9 | Phased approach to achieving appropriate PRA quality and completeness |

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

RS-MS1-1 Reactor Safety Arena

**Implementation Activity:** **Establish and maintain 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/DIPM/IIPB)**

***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 Reactor Oversight Process (ROP) is to monitor licensee performance with respect to reactor safety cornerstones (initiating events, mitigation systems, barrier integrity, and emergency preparedness), radiation safety cornerstones (occupational radiation exposure and public radiation exposure), and security cornerstone. Performance indicators are used to monitor licensee 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 licensee performance. NRC is also inspecting the performance indicator reporting process. The results and lessons learned from ROP implementation are documented in annual reports to the Commission.

| | | |
|---|---|---|
| Assessment Cycle 1 | April 2000 - March 2001 | SECY-01-0114 |
| Assessment Cycle 2 | April 2001 - December 2001 | SECY-02-0062 |
| Assessment Cycle 3 | January 2002 - December 2002 | SECY-03-0062 |
| Assessment Cycle 4 | January 2003 - December 2003 | SECY-04-0053 |

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

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

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

***Strategy 4:*** *Provide a fair and timely process to allow public involvement in NRC decision-making in matters not involving sensitive unclassified, safeguards, classified, or proprietary information.*

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Report on lessons learned from full implementation | June 2001 | | June 2001 |
| Status report on lessons learned from implementation | March 2002 | | April 2002 |
| Annual status report on ROP implementation | March 2003 | April 2003 | April 2003 |
| Annual status report on ROP implementation | April 2004 | | April 2004 |
| Annual status report on ROP implementation | April 2005 | | |

RS-MS1-2 Reactor Safety Arena

**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/DIPM/IIPB)**

***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 Process 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 Reactor Oversight Process (ROP) was developed using the results of research work and previous risk studies to identify the most significant structures, systems, and components (risk matrices) and to develop processes by which 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 determine how we have used risk significant issues in the past.

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

**Project Considerations:** The staff developed a self-assessment process to continue to refine and improve the Reactor Oversight Process to incorporate lessons learned and future risk insights. The staff presented the results of its annual assessment of the ROP in SECY-04-0053 in April 2004.

As a result of the lessons learned from the Davis-Besse plant, the ROP is being revised to account for needed changes in outage activities, inservice inspections, problem identification and resolution, and plant status activities.

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Revise inspection procedures to incorporate lessons learned from initial implementation | January 2002 | | January 2002 |
| Revise inspection procedures to incorporate lessons learned from Davis-Besse Lessons Learned Task Group | March 2004 | January 2005 | |
| Test effectiveness of newly developed inspection procedure for engineering design inspections (SECY-04-0071) | March 2005 | | |

RS-MS1-3 Reactor Safety Arena

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

***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 assessing the importance of inspection findings, the Significance Determination Process (SDP) 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 SDP Phase 2 risk informed notebooks for all operating plants in the nation were benchmarked to address challenges identified with initial implementation of the SDP. During the two-year benchmarking effort that was completed in September 2003, the staff gained insights and incorporated improvements into the Phase 2 benchmarking process. Also, a technical basis document IMC-308, Attachment 3, Appendix A was issued for the Phase 2 SDP process. These improvements created a disparity in the completeness of the Revision 1 notebooks that were completed early in the two-year benchmark process compared to those completed later in the process. Additionally, the determination of large early release frequency (LERF) is required in accordance with IMC-0609, Appendix H. The results from the LERF determinations for all plant-specific risk-informed inspection notebooks will also need to be incorporated into the future development of enhanced presolved tables. Thus, the staff has begun a Revision 2 standardization effort for all the Phase 2 notebooks to include any updated risk information through the use of the technical basis document and use of the improved computer spreadsheets to evaluate and document the results. Completion of the presolved tables is included in the Director's Quarterly Status Report (DQSR).

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.

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

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

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

***Strategy 3:*** *Provide accurate and timely information about the safety performance of the licensees regulated by the NRC.*

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

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

Performance indicator information, inspection findings, and the results of the NRC assessment process are made publicly available 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 continues to evaluate the ROP for lessons learned through a periodic self-assessment process.

A Mitigating Systems Performance Index (MSPI) was jointly developed by NRC staff and industry and was evaluated for implementation. The staff determined that MSPI will be implemented while retaining the SDP for inspection findings. Several technical issues continue to be evaluated which will be resolved prior to implementation.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Maintain and improve Significance Determination Process inspection notebooks (Revision 2) | June 2005 | | |
| Completion of Significance Determination Process Phase 2 Presolved Tables | December 2005 | | |
| Evaluate implementation of the MSPI | January 2004 | March 2004 | July 2004 |
| Implement the MSPI | 2006 | | |

RS-MS3-1 Reactor Safety Arena

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

***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 supports the Reactor Oversight Process (ROP) by:

- Developing the Mitigating Systems Performance Index (MSPI).
- Developing Risk Assessment Standardization Project (RASP) Products.

Developing the Mitigating Systems Performance Index (MSPI)

ROP currently uses performance indicators (PIs) that quantify system unavailability. These PIs have known issues associated with them, which include:

- Use of generic thresholds that do not recognize plant-specific features.
- Use of fault exposure time as a substitute for unreliability.
- Cascading failures of cooling water support systems.

RES has developed the MSPI to address these issues by:

- Calculating unreliability using failure and demand counts, which are a direct measure of reliability, rather than fault exposure time.
- Calculating MSPI as the sum of UAI (system unavailability index due to changes in train unavailability) plus URI (system unreliability index due to changes in component unreliability), which is a simple calculation in comparison to a complete PRA requantification.
- Rolling up most equipment performance data into a single performance-related figure of merit for each system
- Directly measuring the performance of cooling water support systems.
- Providing a very good approximation of the change in CDF due to current performance, provided that changes in performance are not extremely large and that current performance can be estimated accurately.

RES piloted the MSPI against 20 plants, using a procedure that:

- Exercised MSPI guidance provided by licensees.
  - MSPI guidance ensured that the 20 plants represented a reasonable cross section of U.S. plant type, age and design, and reactor manufacturers.
- Performed validation and verification provided by RES.
  - MSPI validation and verification included a plant-by-plant performance data cross-comparison, use of SPAR models to validate importance measures, and identification and resolution of significant issues with the MSPI methodology.
- Performed Temporary Instruction inspections exercise by the RNC Regions.
  - The MSPI Temporary Instruction inspections exercise included an item-by-item verification of many of the tasks performed by the licensees, although not on all systems on all plants.

Overall, the MSPI results from the pilot plant submittals and from SPAR models were found to be in very good agreement.

Developing Risk Assessment Standardization Project (RASP) Products

RES started to develop standard procedures and methods for risk assessments of inspection findings and reactor incidents via the Risk Assessment Standardization Project (RASP).

Under RASP, RES will:

- Develop guidelines for the analysis of internal events during power operations.
- Develop new methods and guidelines for the SDP Phase 3, ASP, and MD 8.3 analysis of internal fires and flooding, external events, internal events during lower power and shutdown operations, and LERF.
- Make SPAR model and GEM enhancements.
- Provide ongoing technical support.

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

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

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

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

RS-MS3-1 Reactor Safety Arena

**Project Considerations:** If implemented, MSPI would support the ROP assessment activities by providing direct measurements of the performance of risk-important safety features to determine whether trends in equipment performance are improving, deteriorating, or remaining constant.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Memo to NRR providing draft report on the MSPI pilot verification for public review and comment. | February 2004 | | February 2004 |
| Memo to NRR providing NUREG report on the MSPI pilot verification. | January 2005 | | |

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RS-MS3-2 Reactor Safety Arena

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

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

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

Under the Industry Trends Support program, RES:

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

Industry Trends are used by:

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

Under the Industry Trends Program in support of the NRC's Action Plan for Resolving Electrical Grid Concerns resulting from the Northeast Electrical Blackout of August 14, 2003, RES started to:

- Update SBO LOOP frequency and duration.
- Reevaluate SBO risk with updated SPAR models for a spectrum of plants.

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

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

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 8

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Updated trends, graphs, and charts for system studies, component studies, common-cause-failure evaluations, and initiating event evaluations through FY 2002 provided on the RES web page. | November 2003 | | November 2003 |
| Using data from recent LOOP events, update SBO LOOP frequency and duration (draft report for internal/external review) re: electrical grid concerns evaluate station blackout implications. | October 2004 | | |
| Updated trends, graphs, and charts for system studies, component studies, common-cause-failure evaluations, and initiating event evaluations through FY 2003 provided on the RES web page. | November 2004 | | |
| Reevaluate SBO risk (CDF) with updated SPAR models for spectrum of plants (draft report for internal/external review) re: electrical grid concerns evaluate station blackout implications. | January 2005 | | |

RS-MS3-3 Reactor Safety Arena

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

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

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

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

- Integrated Data Collection and Coding System (IDCCS)
  - Collects and codes operational data from:
    - < Licensee Event Reports (LERs)
    - < INPO's Equipment Performance and Information Exchange (EPIX) System
    - < Licensees' Monthly Operating Reports.
  - 4. Data collected in the IDCCS are analyzed to produce:
    - < Industry-wide initiating event frequencies.
    - < System reliability estimates (industry-wide and plant-specific) for major risk-significant systems.
    - < Component reliability estimates for major risk-significant components.
    - < Common-cause failure parameter estimates.
    - < Fire event frequencies.
    - < Common-cause failure events insight reports.
  - IDCCS data and their trends are available to NRC staff on:
    - < Reactor Operating Experience Results and Databases web page (http://nrcoe.inel.gov/index.cfm) on the NRC internal web site.
  - IDCCS maintains a library of all LERs with event dates from January 1, 1986, to the present which are available through LERSearch, a system for searching and retrieving LERs by selected fields and text searches of the title, abstract, or full LER.
    - < LERSearch is available to NRC staff on the internal web site at https://nrcoe.inel.gov/secure/LERSearch/index.cfm.
  - IDCCS also:
    - < Identifies candidate events for the RES Accident Sequence Precursor (ASP)Program.
    - < Codes shutdown initiating event data for the Standardized Plant Analysis Risk (SPAR) low-power/shutdown (LP/SD) models.
    - < Identifies LER events involving human performance for the Human Event Repository and Analysis (HERA) database.
- Reliability and Availability Data
  - Reliability and Availability Data System (RADS) which estimates plant-specific and generic component-level reliability, and train level availability. RADS includes input from the Equipment Performance and Information Exchange (EPIX) database, which is maintained by the Institute of Nuclear Power Operations (INPO).

- Accident Sequence Precursors (ASP) Database
  - The Accident Sequence Precursor (ASP) events database which contains summary information on all the ASP events since 1969.

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

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

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

RS-MS3-3 Reactor Safety Arena

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

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

NRC licensees have access to CCF data.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Letter from INEEL stating that the LER search system is fully implemented on the RES web page. | May 2004 | | May 2004 |
| Letter from INEEL stating that the Integrated Data Collection and Coding System first-year trial testing has been completed and that the system is fully implemented. | July 2004 | | July 2004 |
| Letter from INEEL stating that the Integrated Data Collection and Coding System has been maintained with the latest quarterly data available through 08/2004. | September 2004 | | August 2004 |

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RS-MS3-4 Reactor Safety Arena

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

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

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

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

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

ASP analyses are used to support:

- Annual Performance and Accountability Report to Congress via the OCFO (significant precursors) and via NRR/DIPM/IIPB (adverse industry trend).
- Industry trends program by NRR/DIPM/IIPB.
- Annual SECY paper to the Commission on the status of the ASP program.
- Studies by RES/DSARE/REAHFB to determine the safety significance of potential regulatory issues.

ASP techniques were recently used to analyze:

- The barrier-integrity and mitigating systems issues at Davis-Besse.
- LOOP events from the Northeast Blackout of August 14, 2004.

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

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

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

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

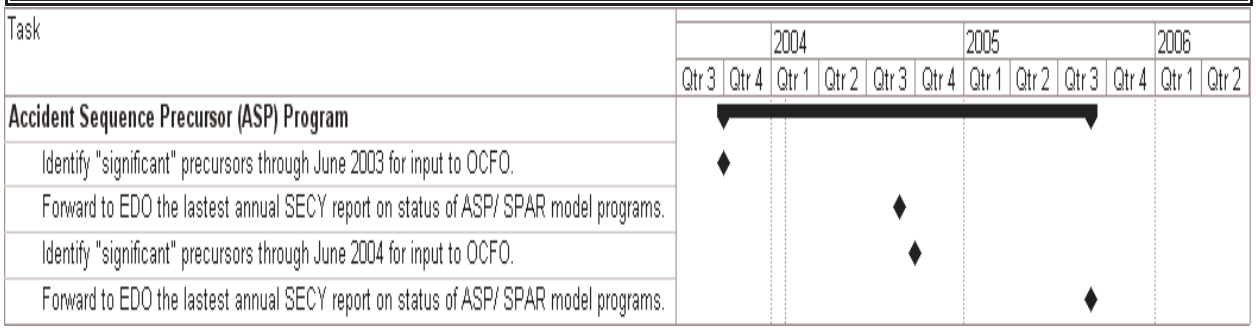
***Strategy 4:*** *Use realistically conservative safety-focused research programs to resolve safety-related issues.*

**Primary Priority:** 1
**Secondary Priority:** 8

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Provide input for OCFO on (1) significant precursors through June 2003; (2) significant radiation overexposures from nuclear reactors for FY 2003; and (3) significant releases to the environment for FY 2003. | December 2003 | | October 2003 |
| Make preliminary ASP analyses of LOOP events from the Northeast Blackout of August 14, 2004, available for technical review (internal/external) re: electrical grid concerns, short-term insights.<br><br>Note: Accidently listed under Activity 1GAA (Industry Trends Support) in FY2004 RES Operating Plan. | March 2004 | | March 2004 |
| Forward to the EDO the annual SECY report on the status of the ASP program and the SPAR model development program. (WITS 199200101) | September 2004 | | September 2004 |
| Provide input for OCFO on significant precursors through June 2004. | October 2004 | | |
| Forward to the EDO the annual SECY report on the status of the ASP program and the SPAR model development program. (WITS 199200101) | September 2005 | | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



RS-MS3-5 Reactor Safety Arena

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

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

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

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

- Level 1 Models for Full Power Operation.
- Models for Low Power and Shutdown (LP/SD) Mode of Operation.
- Models for Performing Large Early Release Frequency (LERF) Calculations.
- Models for External Events (Fires, Floods, Seismic Events, High Winds, etc.).
- SDP Front-End Interface for SPAR Models, for use with SAPHIRE and GEM codes.

SPAR models are used to:

- Evaluate Risk Significance of Inspection Findings in SDP Phase 3 Analyses.
- Evaluate Risk Associated with Operational Events/Conditions in ASP Program.
- Improve the Quality of PRAs.
  2. Identify modeling issues that are risk-significant, and rank and prioritize these issues as part of the PRA quality efforts (e.g., as part of R.G. 1.200).
- Perform Analyses in Support of Generic/Safety Issue Resolution (e.g., GSI-189 and GSI-191):
  - Screening (or prioritization) analysis.
  - Detailed analysis to:
    - < Determine if licensees should be required to make change(s) to their plants.
    - < Assess whether NRC should modify or eliminate an existing regulatory requirement.
  - Flexible and quick analyses result in minimum resources required to perform generic studies.
- Perform Analyses in Support of the Staff's Risk-Informed Review of License Amendments (e.g., Tech Spec Changes, NOEDs, Fire-Protection Requirements).

- Independently Verify Mitigating Systems Performance Index (MSPI).

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

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

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

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

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

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

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

***Strategy 8:*** *Make timely regulatory decisions.*

**Primary Priority:** 1
**Secondary Priority:** 3

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Document Revision 3 SPAR model development project accomplishments from 9/2003 to 8/2004. | September 2004 | | September 2004 |
| Document LERF SPAR models completed from 09/2003 through 08/2004. | September 2004 | | September 2004 |
| Document LP/SD SPAR models completed from 09/2003 to 08/2004. | September 2004 | | September 2004 |
| Document Revision 3 SPAR model development project accomplishments from 9/2004 to 8/2005. | September 2005 | | |
| Document LERF SPAR models completed from 09/2004 through 08/2005. | September 2005 | | |
| Document LP/SD SPAR models completed from 09/2004 to 08/2005. | September 2005 | | |

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RS-MS8-1 Reactor Safety Arena

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

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

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

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

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

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

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

The staff received 26 sets of comments containing hundreds of individual comments. The staff worked to address and resolve those comments and incorporated the responses to the proposed rule comments into the final rulemaking package. In November 2003, the staff

received draft revision D of NEI 00-04. Later, in April 2004, the staff received the final draft of NEI 00-04. The staff reviewed these drafts and developed RG 1.201 (formerly DG-1121) that endorses the NEI guidance with exceptions. Given the significance of some of the exceptions, the staff decided to issue RG 1.201 for trial use. RG 1.201 was also provided as part of the final rulemaking package.

Development of the final rulemaking package for § 50.69 was completed and went into rulemaking concurrence in April 2004. The staff had a successful meeting with the ACRS on June 2, 2004, and the ACRS subsequently provided a letter dated June 15, 2004 (ML041690039) recommending issuance of the final rule and RG 1.201 (for trial use). By letter dated June 15, 2004 (ML041680535), the CRGR decided not to review the final rulemaking package. The final rulemaking package (SECY-04-0109) for § 50.69 was sent to the Commission on June 30, 2004. The Commission approved the final rule, with some modifications, in an affirmation session on October 7, 2004.

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

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

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

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

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

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

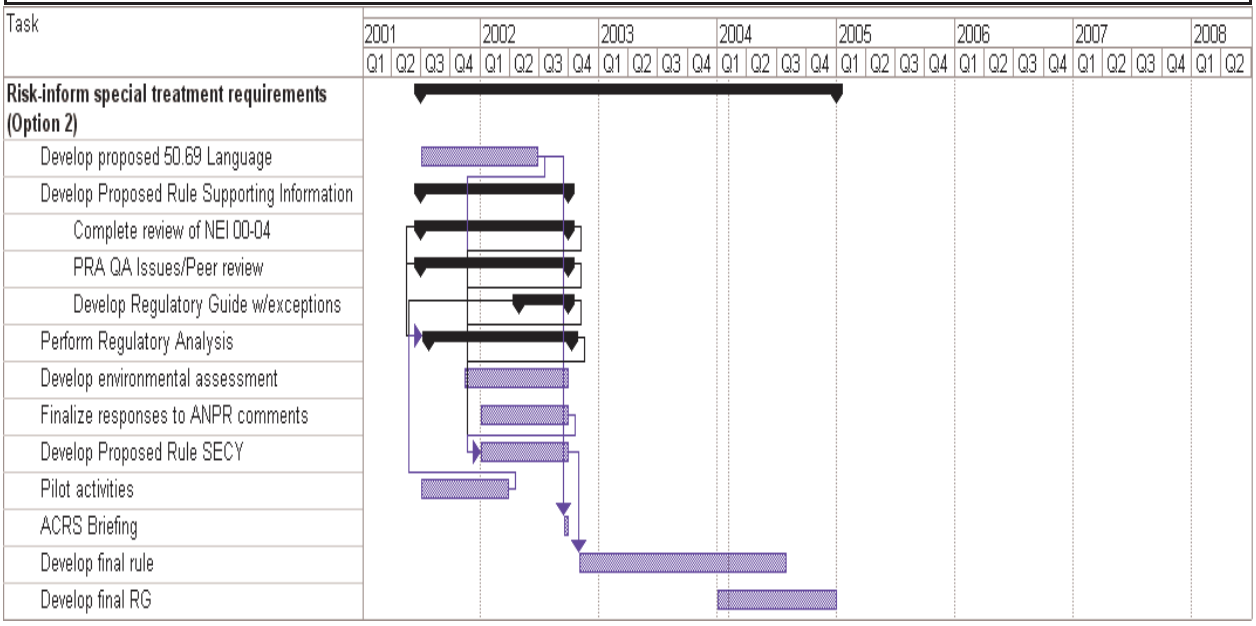
**Primary Priority:** 6
**Secondary Priority:** 8

RS-MS8-1 Reactor Safety Arena

**Project Considerations:**

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Proposed Rule | August 2001 | September 2002 | September 2002 |
| Final Rule | December 2002 | June 2004 | June 2004 |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



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RS-MS8-3 Reactor Safety Arena

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

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

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

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

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

In SECY-01-0133, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10CFR50.46 (ECCS Acceptance Criteria) and SECY-02-0057 (update to SECY-01-0133), the staff recommended rulemaking to change the technical requirements for the emergency core cooling systems (ECCS). The staff recommended that separate rulemakings be pursued for proposed changes to: 1) ECCS functional reliability requirements, 2) ECCS acceptance criteria, and 3) ECCS evaluation model requirements.

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

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

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

1. Complete technical work on LOCA frequency estimation by March 31, 2004
2. Prepare a proposed rule to allow for a risk-informed alternative to the present maximum break size by March 31, 2004

3. Prepare a proposed rule with a performance-based approach to meeting ECCS acceptance criteria by March 31, 2006.
4. Proceed with rulemaking to risk-inform ECCS functional reliability requirements in GDC 35 and thus relax the current requirement for consideration of a large break LOCA with a coincident LOOP by July 31, 2004.
5. Pursue a broader change to the single failure criterion and inform the Commission of its findings by July 31, 2004.

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

In response to this SRM, the staff prepared SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of-Offsite Power" dated March 2004, in which the staff requested direction and additional guidance on policy issues that would facilitate resolution of identified technical issues. The technical issues include (1) the alternate break size selection matrix, (2) appropriate limitations on what modifications would be allowed in a plant and how they could change the risk profile, (3) defense-in-depth considerations, and (4) the appropriate level of mitigative capability which should remain for breaks beyond the new design basis.

In May 2004, anticipating Commission direction on these issues, the staff established a Steering Committee (headed by Brian Sheron, ADPT) to direct and coordinate an expedited effort to issue a proposed rule. On July 1, 2004, the Commission issued its SRM on SECY-04-0037 stating that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than this size should be removed from the design basis event category. The Commission indicated that the proposed rule should be broadly structured to allow operational as well as design changes and should include requirements for licensees to maintain capability to mitigate the full spectrum of LOCAs up to the double-ended guillotine break of the largest reactor coolant system pipe. The Commission stated that the mitigation capabilities for beyond design-basis events should be controlled by NRC requirements commensurate with the safety significance of these capabilities. The Commission stated that LOCA frequencies should be periodically reevaluated and should increases in frequency require licensees to restore the facility to its original design basis or make other changes, the backfit rule (10 CFR 50.109) would not apply. The Commission also directed the staff to complete the proposed rule in 6 months.

In late July 2004 the staff completed a narrative description of the conceptual basis for the proposed rule on LOCA Redefinition and draft rule language, both of which were posted on the NRC public website on August 2, 2004. A notice of availability of this information was published in the *Federal Register* on August 2, 2004. The notice also informed stakeholders of a public meeting that was held on August 17, 2004, to obtain cost/benefit information on the planned approach for use in the Regulatory Analysis for the proposed rule.

In SECY-04-0037, the staff recommended finishing review of the topical report and pilot exemption requests on LOCA-LOOP before developing a rulemaking plan. On April 27, 2004, the BWROG submitted the topical report for NRC review. In the July 1 SRM, the Commission agreed that the NRC staff should first evaluate the pilot exemption request before proceeding

with a separate rulemaking on LOCA-LOOP. NRC completed its acceptance review of the report on July 20, 2004, concluding that the material was sufficient for further evaluation. The staff will begin active review of the report after the proposed rule on LOCA Redefinition is sent to the Commission. Review of the report is expected to take approximately 14 months.

The Commission approved the staff recommendation to develop a rule for performance-based ECCS acceptance criteria applicable to cladding materials other than zircaloy or ZIRLO™. Due to other priorities and the ongoing research work that will support the rule, this effort is not scheduled to begin until FY05.

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

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

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original RIRIP Target Date** | **Revised Date** | **Completion Date** |
| Complete proposed rule defining alternative, risk-informed option ECCS evaluation criteria and risk-informed acceptance criteria for associated plant design and operational changes | 12 months after 1st SRM (03/31/2004) | 6 months after 2nd SRM (12/31/2004) | |
| Completion of BWR safety evaluation LOCA/LOOP exemption request topical report | August 2006[1] | | |
| Complete proposed rule (LOCA/LOOP) and issue for public comment | March 2007 | | |

[1] Completion date subject to resolution of issues arising from pilot plant submittal reviews.

RS-MS8-4 Reactor Safety Arena

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

***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," December 23, 1998, the staff proposed options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. Option 3 identified possible changes to specific technical requirements in Part 50. The Commission approved the staff's proposal in a June 8, 1999, Staff Requirements Memorandum (SRM).

In SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendation on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)'", the staff recommended the development of risk-informed approaches to technical requirements in 10 CFR 50.46 (and related provisions) concerning LOCA acceptance criteria and evaluation models. In its March 31, 2003, SRM in response, the Commission directed the staff to undertake a number of rulemakings, one of which was to prepare a proposed rule to allow, as a voluntary alternative, a redefinition of (design basis) large break LOCA maximum break size. SECY-04-0060, "Loss-of-Coolant Accident Break Frequencies for the Option III Risk-Informed Reevaluation of 10 CFR 50.46, Appendix K to 10 CFR Part 50 and General Design Criteria (GDC)", April 13, 2004, provided a summary of preliminary redefined LOCA frequencies.

Numerous technical challenges must be overcome prior to a rule impacting emergency core cooling requirements becomes finalized. These challenges include: developing an appropriate alternate maximum break size risk metric, appropriate limitations on what can be modified in a plant, controlling the total risk change, establishing the potential for "reversal" of changes, appropriate PRA scope, extent of redefinition of large break LOCA throughout the rest of Part 50, defense-in-depth considerations, and establishing mitigation capability to be retained for break sizes between the new maximum design basis LOCA size and the double-ended guillotine (DEG) break of the largest pipe in the system. These issues were addressed in SECY 04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-Of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-Of-Offsite Power", March 3, 2004. In its SRM, dated July 1, 2004, the Commission reiterated its desire to risk-inform the requirements addressing large break loss-of-coolant accidents (LOCA) and it directed the staff to complete the development of the proposed rule by December 2004.

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

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

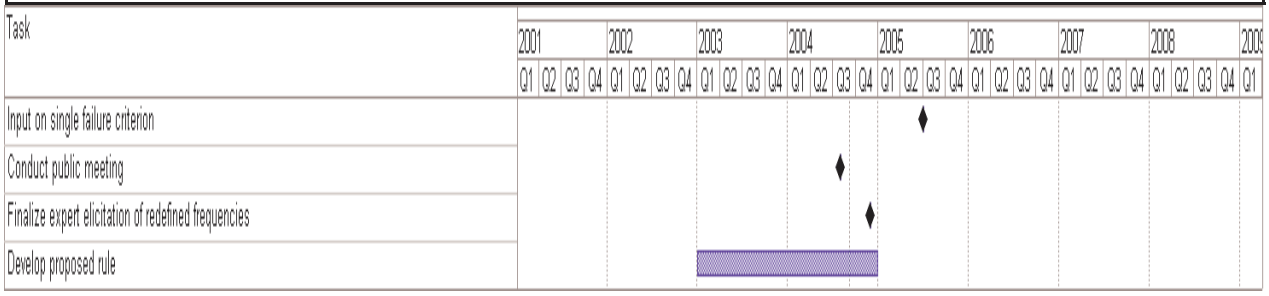
***Secondary FY 04-09 Strategic Plan Goal****: Ensure protection of public health and safety and the environment.*

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

**Primary Priority:** 3
**Secondary Priority:** 6

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Preliminary redefined LOCA frequencies | April 2004 | | April 2004 |
| Complete expert elicitation for final LOCA frequencies | December 2004 | | |
| Input on single failure criterion | July 2004 | July 2005 | |
| Conduct public meeting to discuss draft rule on 50.46 | August 2004 | | August 2004 |
| Submit proposed rule on 50.46 | December 2004 | | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



RS-MS8-5 Reactor Safety Arena

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

***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 industry continue to develop risk-informed improvements to the current system of standard technical specifications (STS). These improvements are intended to maintain or improve safety while reducing unnecessary burden and to bring technical specification requirements into congruence with the Commission's other risk-informed regulatory activities.

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

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.

Each initiative can involve some combination of: a topical report approving the generic change; an STS change proposal with a TSTF-### designator; a pilot plant to test the change; and, a Consolidated Line Item Improvement Process (CLIIP) package (described in NRC Regulatory Issue Summary 2000-06, "Consolidated Line Item Improvement Process For

Adopting Standard Technical Specifications Changes for Power Reactors," for reviewing and implementing improvements to the STS). The four owner's groups may or may not consolidate efforts into a single submittal. The following table on "Selected Major Milestones and Schedules" reflects upcoming targeted completion dates.

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

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

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

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

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

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

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

**Primary Priority:** 1
**Secondary Priority:** 3

RS-MS8-5 Reactor Safety Arena

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Initiative 1 - Approve TSTF-422 for CE plants and make available via CLIIP | September 2003 | December 2004 | |
| Initiative 1 - Approve TSTF-423 for BWR plants and make available via CLIIP | March 2005 | | |
| Initiative 1 - Write safety evaluation for B&W Topical Report | December 2004 | | |
| Initiative 1 - Approve TSTF-431 for B&W plants and make available via CLIIP | June 2005 | | |
| Initiative 4 - Industry submit revised Risk Management Guide, TSTF-424, and STP pilot amendment. | June 2004 | December 2004 | |
| Initiative 5 - Industry submit methodology document, Limerick pilot amendment and TSTF-425 | March 2004 | December 2004 | |
| Initiative 5 - Approve methodology document, Limerick pilot amendment and TSTF-425 | October 2005 | | |
| Initiative 6 - Approve and issue safety evaluation for CE PWRs | September 2004 | | July 2004 |
| Initiative 6 - Approve TSTF-426 and make available via CLIIP | December 2004 | | |
| Initiative 7 - Staff provide feedback to industry on TSTF -372 (snubbers) and TSTF-427 (hazard barriers) | April 2004 | | April 2004 |
| Initiative 7 - Approve TSTF -372 (snubbers) and write safety evaluation | September 2004 | | September 2004 |
| Initiative 7 - Make TSTF -372 (snubbers) available via CLIIP | December 2004 | | |
| Initiative 7 - Approve TSTF -427 (hazard barriers) and write safety evaluation | October 2005 | | |
| Initiative 7 - Make TSTF -427 (hazard barriers) available via CLIIP | December 2005 | | |
| Initiative 8 | TBD | | |

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RS-MS8-6 Reactor Safety Arena

**Implementation Activity: Fire protection for nuclear power plants. (NRR/DSSA/SPLB)**

***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: Post-Fire Safe-Shutdown Circuit Analysis Resolution Program**
Another activity related to fire protection is the Circuit Analysis Resolution Program. In response to the need to resolve concerns associated with post-fire safe shutdown, fire-induced circuit failure analysis issues, the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) have respectively developed deterministic and risk-based post-fire safe shutdown methodology documents. These two documents have been combined into one document which provides a means of determining the potential risk for associated circuit failure during a postulated fire as a part of the safe shutdown analyses. NEI has completed a series of fire tests which provided insights to electrical cable performance and subsequent failures during a thermal insult.

NEI also assembled and completed the work of an Expert Panel to evaluate the test results. This work was published by EPRI in May 2002 as “Spurious Actuation of Electrical Circuits due to Cable Fires.” (EPRI Report #1006961) NEI submitted NEI 00-01, “Guidance for Post-Fire Safe Shutdown Analysis,” Draft Revision, D to the staff in October 2002. The staff has reviewed this document and plans to endorse the document in the regulatory guide supporting the NFPA 805 rule. The staff plans to endorse this document for Appendix R, after taking exceptions to some issues that are contrary to the current agency rules and positions.

In February 2003, NRR held a facilitated workshop to discuss Risk-Informing the Post-Fire Safe-Shutdown electrical circuit inspections. The purpose of this workshop was to exchange information with our stakeholders concerning risk-informing the inspections. The staff held a workshop for a number of regional inspectors in July 2004. The staff issued RIS 2004-03 on March 2, 2004, to discuss risk-informing this process. The staff is currently revising the inspection procedure, and another public workshop is scheduled for the fourth quarter of 2004 to discuss how the associated circuit inspections will be risk-informed.

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 6

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Workshop for regional inspectors | July 2004 | | July 2004 |
| Hold public workshop | December 2004 | | |

RS-MS8-7 Reactor Safety Arena

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

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

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

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

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

A peer review of this work is currently underway, and a final report will be issued in 2004. This report will incorporate comments and suggestions provided by the review and other confirmatory work currently in progress.

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 6

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Final report with detailed description of PRA analysis methods and results for peer review | October 2003 | | October 2003 |
| Peer review of the Final Report on recommended changes in PTS screening criteria. | June 2003 | November 2004 | |
| Final report on recommended changes associated with PTS screening criteria. | September 2003 | December 2004 | |

RS-MS8-8 Reactor Safety Arena

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

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

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

The staff has developed a PRA plan for the development of methods, data, and tools needed for reactor-specific PRAs to support the evaluation of the design and operational characteristics of advanced reactors that are different from those of current reactors. The PRA plan considers such things as the quantification of initiating events, likely accident phenomena, accident progression, containment-confinement performance, passive systems, digital instrumentation and control systems, uncertainties, internal flooding, external events (fires and seismic events), and multiple reactor modules on a site. The plan has been implemented. Work is continuing on the generic PRA aspects for advanced reactors, as well as on design-specific reviews, e.g., ACR-700. FY05 funding is supporting investigation of passive system modeling and data collection activities for application to generic advanced reactor PRAs. The ACR-700 pre-application PRA methodology review of six PRA documents from AECL to identify strengths and weaknesses has been completed. The report documenting the findings has been issued to NRR. A report has been issued to NRR that identifies the initiating events that should be considered for the ACR-700. This report considered initiating events typical of the current U.S. PWR nuclear power plants, those identified by AECL for the CANDU 6 reactors, and those proposed by AECL for the ACR-700. FY05 activities will involve incorporation of ACR-700 specific information, as it becomes available, to provide ACR-700 specific results to support other areas of research, such as thermal/hydraulics (success criteria), and severe accident progression (accident sequence and source term identification).

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 6

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| ACR-700 Report on the strengths and weaknesses of the AECL PRA methodology, based on the PRA methodology used in the CANDU6 and CANDU9 reactor designs. | March 2004 | | March 2004 |

RS-MS8-9 Reactor Safety Arena

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

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

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

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

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

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 1

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

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

RS-MS8-10 Reactor Safety Arena

**Implementation Activity: Develop Structure for New Plant Licensing (RES/DRAA/PRAB)**

***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 and implemented a plan to develop a structure for new plant licensing. The effort includes four major parts:

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

The work to date has focused on the development of the technology-neutral framework (part 1). The staff has held public meetings, internal management meetings, a public workshop, and briefed the ACRS on the staff progress. The framework structure is a top-down approach which delineates the process of how the mission of the atomic energy act of protecting the public health and safety is translated into a set of technology-neutral requirements. What guidance and criteria for implementing the process has been identified which includes:

- safety philosophy
- risk expectations
- design expectations
- treatment of uncertainties

Preliminary initial guidance has been developed for each of these issues. Initial feedback from stakeholders has been positive. The ACRS indicated that “the staff is on the right track, asking the right questions.” A complete draft framework is scheduled to be issued in December 2004 for formal public review and comment.

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

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

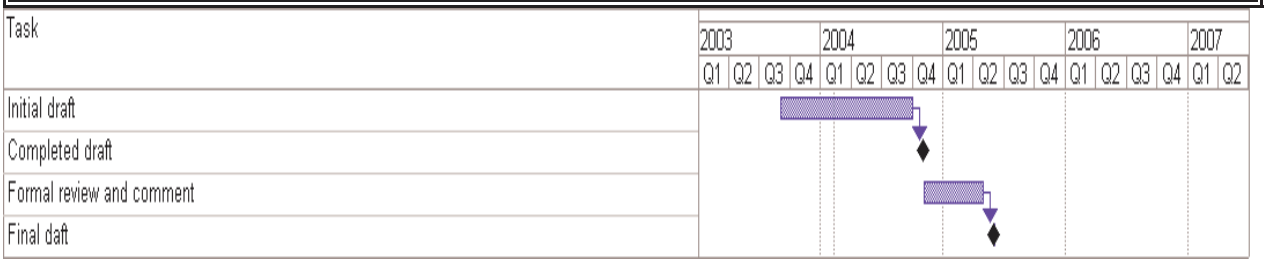
***Secondary FY 04-09 Strategic Plan Goal**: Ensure openness in our regulatory process.*

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

**Primary Priority:** 3
**Secondary Priority:** 10

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Complete initial draft framework for offsite meeting | February 2004 | | February 2004 |
| Complete draft framework for Commission and issue for public review and comment | December 2004 | | |
| Issue final framework | June 2005 | | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



RS-EER1-1 Reactor Safety Arena

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

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

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

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

Phase One was designed to gather insight into staff perceptions of risk-informed regulatory practices, identify barriers to implementing risk-informed approaches, and target ideas that facilitate successful risk-informed processes. An evaluation report (ADAMS # ML022460161), completed in August 2002 characterized common themes agreed upon by NRR staff and management and outlined systemic challenges related to risk-informed work activities and processes. The report was widely distributed in hard copy within NRR and the regions, and the RIE team conducted presentations to management teams in NRR, to divisions across the reactor program, and to several NRC professional conferences during the summer and fall of 2002. The evaluation report identified barriers to implementing risk-informed approaches as well as catalysts for achieving successful risk-informed processes.

The second phase of the program involved several pilot projects and other follow-up activities. The formal objectives for phase 2 were to (1) define the components of a risk-informed environment by accumulating lessons learned from addressing the environmental needs of several current specific technical activities being risk-informed within NRR and (2) provide concrete assistance in one or more areas of communications, training or organization to the participating technical activities to support broad implementation of the activities throughout the reactor program. The following activities were completed:

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

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

Phase 2 has been completed. A report documenting the findings from phase 2 has been completed. The report clearly lays out the critical elements of a risk-informed environment and approaches for establishing those elements in the reactor program. A plan for implementing changes in the reactor program to enhance the current environment for risk-informed regulation has been developed. The plan was presented to the NRR Leadership Team in July 2004. The leadership team is currently considering which, if any, of the initiatives proposed in the plan to pursue in FY05.

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

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

***Strategy 8:*** *Make timely regulatory decisions.*

**Primary Priority:** 3

**Project Considerations:**

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Evaluate current environment for implementing risk-informed regulation in the reactor program, including current policies, practices, information base, methods and channels of communication, and staff and management perspectives. | December 2001 | February 2002 | February 2002 |
| Complete pilot projects | October 2003 | | October 2003 |
| Develop target environment | December 2003 | | January 2004 |
| Implement appropriate changes in NRR activities | March 2005 | December 2005 | |
| Assess Effectiveness | October 2004 | December 2007 | |

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

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

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

The increased use of probabilistic risk assessments (PRA) in the regulatory decisionmaking process requires consistency in the quality, scope, methodology and data used in such analyses. These requirements apply to PRAs developed by industry to support specific, risk-informed licensing actions as well as to PRAs developed by NRC staff to analyze specific technical issues or to support Commission decisions. To this end, NRC worked with the American Society of Mechanical Engineers (ASME) to develop a national consensus standard setting forth specific guidance regarding the construction and execution of a PRA covering internal initiating events (excluding internal fire) at full power operation for a level 1 and limited level 2 (large early release frequency only) PRA. This standard, which was issued in April 2002 and updated in December 2003, will help to ensure that PRAs developed in accordance with the standard are robust, consistent, and defensible and are documents from which regulatory decisions can confidently be made. The staff is continuing to work with ASME to develop a revision to the standard which was initiated following a trial use at the San Onofre Nuclear Generating Station. This revision is expected to be issued in early 2005.

The NRC staff has also been working with the American Nuclear Society (ANS) to develop a companion standard covering probabilistic analyses that would include the risk of internal fire, the impacts of external events on plant risk, and risk-significant events that could occur when a plant is operating at low power or when shutdown (LP/SD). ANS has published a PRA standard on external events,(*American National Standard External Events PRA Methodology, ANSI/ANS-58.21-2003*), December 2003. In parallel, the staff also worked with the National Fire Protection Association (NFPA) to develop standards for fire risk analysis (See activity RS-MS8-6).

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

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

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

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

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

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

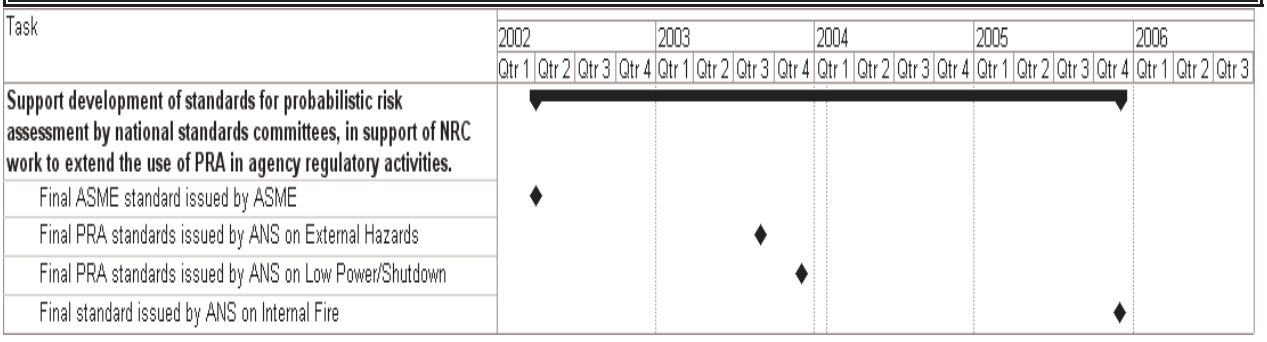
***Strategy 3:*** *Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.*

**Primary Priority:** 3
**Secondary Priority:** 6

**Project Considerations:** This RG will be evaluated as part of the staff's plan to implement a phased approach to PRA quality.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones[2]** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Final PRA standard issued by ASME | March 2001 | March 2002 | April 2002 |
| Final PRA standards issued by ANS on External Hazards | June 2002 | September 2003 | December 2003 |
| Final PRA standards issued by ANS on Low Power/Shutdown | June 2002 | TBD | |
| Final standard issued by ANS on Internal Fire | December 2004 | December 2005 | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**




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

RS-EER1-3 Reactor Safety Arena

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

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

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

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

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

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

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

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

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

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

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

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

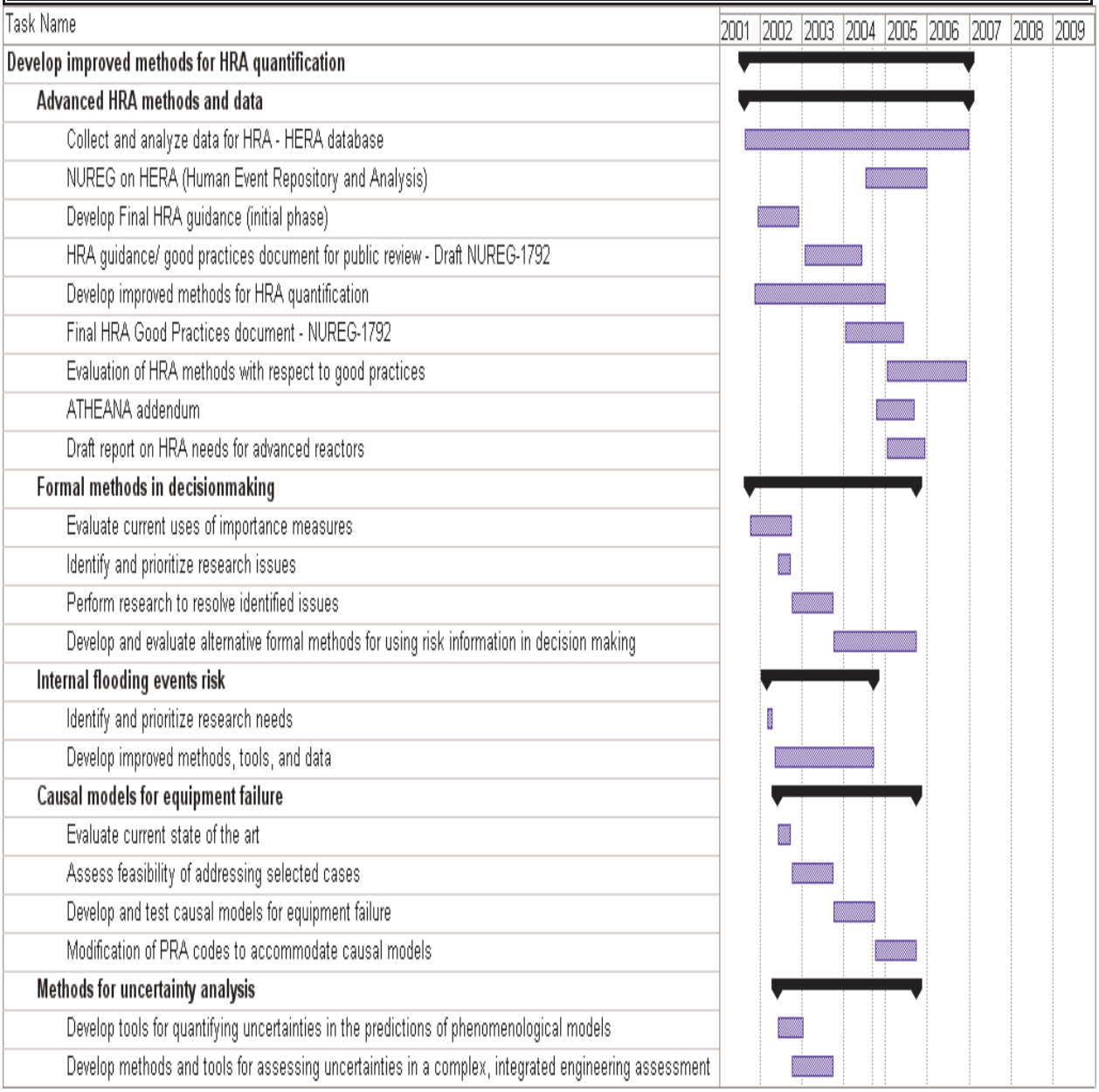
**Primary Priority:** 3
**Secondary Priority:** 6

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Support international (CNSI and Halden) HRA activities on the identification of HRA data deeds. | September 2003 | | September 2003 |
| Convene seventh international cooperative PRA research program meeting | September 2003 | | September 2003 |
| Develop a prototype extraction tool allowing utilization of various HRA data sources. | December 2003 | | December 2003 |
| Letter report on HRA data repository entitled Human Event Repository and Analysis (HERA) | September 2004 | December 2004 | |
| Populate HERA with Licensee Event Reports related to human performance | December 2004 | ongoing effort | |
| Develop Bayesian approaches for estimating Human failure event probabilities using HERA | December 2005 | | |
| Support the international activities (CNSI and Halden) HRA data development | December 2004 | ongoing effort | |
| Complete development of HRA guidance / HRA “Good practices” document for public review | December 2003 | | December 2003 |
| NUREG-1792, “Good Practices for Implementing Human Reliability Analysis (HRA), Draft for Report Comment” - final phase | September 2004 | December 2004 | |
| Publish NUREG-1792, “Good Practices for Implementing Human Reliability Analysis (HRA)” | April 2005 | | |
| Letter Report on the evaluation of current HRA methods with respect to HRA Good Practices | December 2005 | | |

| | | | |
|---|---|---|---|
| Addendum to NUREG-1624, " A Technique for Human Event Analysis (ATHEANA)" documenting improvements made to ATHEANA on the basis of lessons-learned using ATHEANA to address regulatory issues (e.g., PTS, and fire analyses) | December 2005 | | |
| Identify HRA needs for advanced reactors | December 2005 | | |

## Implementation Activity Gantt Charts Calendar Year



RS-EER1-4 Reactor Safety Arena

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

***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. A fire risk program has been developed and is being implemented to address the complex issues associated with fire risk, and to support risk-informed changes to these standards and regulations.

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

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

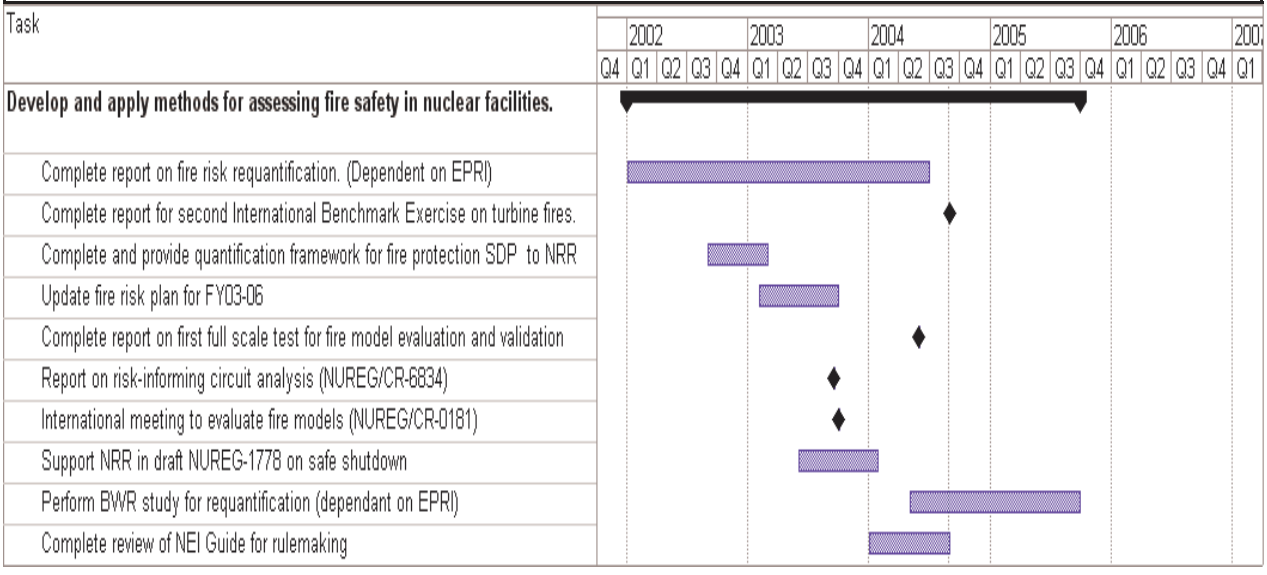
***Secondary FY 04-09 Strategic Plan Goal***: *Ensure protection of public health and safety and the environment.*

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

**Primary Priority:** 3
**Secondary Priority:** 6

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original RIRIP Target Date** | **Revised Date** | **Completion Date** |
| Provide quantification framework for fire protection SDP to NRR | March 2003 | | March 2003 |
| Updated plan for fire risk | June 2003 | | June 2003 |
| Complete report for second International Benchmark Exercise on turbine hall fires. | September 2003 | December 2004 | |
| RES technical response to User Need NRR-2003-002 on associated circuits inspection items. | December 2003 | | December 2003 |
| Fire protection SDP revision according to User Need NRR-2002-027 | February 2004 | | February 2004 |
| Complete fire model verification and validation documents. | December 2004 | | |
| Complete report for third international benchmark exercise on cable tray tests. | December 2004 | August 2005 | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



RS-EER1-5 Reactor Safety Arena

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

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

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

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

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

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

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

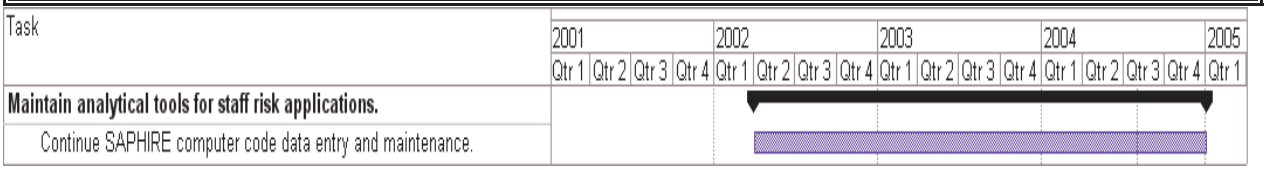
***Strategy 3:*** *Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.*

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

**Primary Priority:** 3
**Secondary Priority:** 6

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



RS-EER1-7 Reactor Safety Arena

**Implementation Activity:** **Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications. (RES/DRAA/PRAB & 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 NRC is extensively using information from probabilistic risk assessments (PRAs) in its regulatory decisionmaking. To streamline staff review of licensee applications using risk insights, professional societies and the industry undertook the following initiatives to establish consensus standards and guidance on the use of PRA in regulatory decisionmaking:

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

It is expected that licensees will use the PRA standards and industry guidance to help demonstrate and document the adequacy of their PRAs for a variety of risk-informed regulatory applications. Therefore, the staff should document its position on the adequacy of the standards and industry guidance to support regulatory applications. Such documentation will indicate in which areas staff review can be minimized and where additional review may be expected. To accomplish this, the staff has developed RG 1.200 to provide an approach for assessing the adequacy of PRA results used in support of regulatory applications and an accompanying Standard Review Plan (SRP) chapter, and will be tested via several pilot plants:

- Columbia - DG AOT extension
- San Onofre - battery AOT extension
- Surry - 50.69 (charging and CCW systems)
- Limerick - TS 5b (surveillance test interval extension)
- South Texas - TS 4b (flexible AOTs)

RG 1.200 and associated SRP chapter are intended to support all risk-informed activities. The staff's position on each PRA standard and industry guidance will be provided in the appendices. To help support these efforts, the staff has also developed a data handbook for probabilistic risk assessments. The Data Handbook defines methods and tools for data analysis used in risk assessments. Additionally, the staff has revised NUREG/CR-6595, "An Approach for Estimating Frequencies of Various Containment Failure Modes and Bypass Events" to expand the approach for estimating large early release frequency (LERF) to include low power/shutdown conditions.

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 6

**Project Considerations:** This RG will be evaluated as part of the staff's plan to implement a phased approach to PRA quality.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones[3]** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Final Reg Guide for trial use | December 2003 | February 2004 | February 2004 |
| Appendix C: Staff position on PRA standards issued by ANS on External Hazards (draft) | December 2003 | August 2004 | August 2004 |
| Appendix D: Staff position on standards issued by ANS on Low Power/Shutdown | December 2004 | December 2005 | |
| Appendix E: Staff position on PRA standards issued by ANS on internal fire | December 2005 | June 2006 | |
| Reg Guide, Rev. 1 | December 2005 | | |
| EDO update of draft NUREG/CR-6595 | March 2003 | December 2003 | December 2003 |
| Final PRA Data Handbook | March 2003 | September 2003 | September 2003 |

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**

| Task Name | 2003 Half 2 | 2003 Half 1 | 2003 Half 2 | 2004 Half 1 | 2004 Half 2 | 2005 Half 1 | 2005 Half 2 | 2006 Half 1 | 2006 Half 2 |
|---|---|---|---|---|---|---|---|---|---|
| **Develop Reg Guide and SRP to provide an approach for characterizing quality of PRA results** | | | | | | | | | |
| Draft Develop Reg Guide and Standard Review Plan | | | | | | | | | |
| Draft Develop RG/SRP Appendix A: staff position on ASME standard | | | | | | | | | |
| Draft Develop RG/SRP Appendix B: staff position on industry guidance | | | | | | | | | |
| Final Reg Guide, Appendix A and Appendix B (for trial use) | | | | | | | | | |
| Develop RG/SRP Appendix C: staff position on ANS external hazards standards | | | | | | | | | |
| Develop RG/SRP Appendix D: staff position on ANS low power/shutdown standards | | | | | | | | | |
| Develop RG/SRP Appendix E: staff position on PRA standards | | | | | | | | | |
| - **Support Activities** | | | | | | | | | |
| Final PRA data handbook | | | | | | | | | |
| EDO update of draft NUREG/CR-6595 | | | | | | | | | |

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RS-EER1-8 Reactor Safety Arena

**Implementation Activity: Coherence Program for Reactor Safety Arena (NRR/DSSA/SPSB & RES/DRAA/PRAB)**

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

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

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

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

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

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

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

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

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 6

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Update plan and issue for internal management review | December 2004 | | |
| Issue Rev. 1 of plan for implementation | April 2005 | | |

RS-EER1-9 Reactor Safety Arena

**Implementation Activity:** **Phased approach to achieving appropriate PRA quality and completeness (NRR/DSSA/SPSB & RES/DRAA/PRAB)**

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

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

In an SRM on COMNJD-03-0002 "Stabilizing the PRA Quality Expectations and Requirements," dated December 18, 2003, the Commission approved implementation of a phased approach to achieving an appropriate quality for PRAs for NRC's risk-informed regulatory decisionmaking. The SRM directed the staff to engage our stakeholders and develop an action plan that defines a practical strategy for the implementation of the phased approach to PRA quality.

The objectives of the SRM are to:

- Move industry in the direction of better, more complete PRAs
- Introduce efficiencies into the staff's review of risk-informed applications
- Allow the staff to establish PRA quality expectations for 10 CFR 50.46 and 10 CFR 50.69 that may be less stringent than required by the March 31, 2003 SRMs.

The SRM specifies four phases for the NRC staff's efforts. The phase we are in is determined by the availability of the PRA guidance documents (e.g., quality standards, industry guides, regulatory guides) needed to generate the results/decision required for an application. We are currently in Phase 1. Phase 2 will be achieved in stages, as the application quality needs are identified and the guidance documents become available for the specific application types. For Phase 2, the scope of the PRA required is a function of the decision to be made (e.g., 50.69, AOT extensions.) To complete Phase 3 the staff will produce (by December 31, 2008) an all-encompassing umbrella guidance document regarding PRA quality for risk-informed applications. Attributes of this guidance document include:

- Ensure consistency among application-specific guidance
- Cover all current risk-informed applications
- Reflect the state-of-the-art
- Allow staff to perform a single PRA review for all applications

Phase 4 calls for the industry to have full scope, full quantification, full uncertainty analyses PRAs that would be reviewed and approved by the NRC. The Commission did not set a date for implementation of Phase 4.

The staff has developed an action plan, as directed, and it was provided to the Commission in July 2004 as SECY-04-0118.

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

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

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

***Strategy 4:*** *Provide a fair and timely process to allow public involvement in NRC decision-making in matters not involving sensitive unclassified, safeguards, classified, or proprietary information.*

**Primary Priority:** 3
**Secondary Priority:** 5

**Project Considerations:** By its nature, this project is closely tied to almost every other activity in the reactor safety arena. NRR and RES staff are working closely together on this project and will continue to coordinate with the other activities.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Provide action plan to the EDO | June 2004 | | July 2004 |
| Implement Phase 3 | December 2008 | | |

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# CHAPTER 2. NUCLEAR MATERIALS AND WASTE SAFETY ARENAS

**Martin J. Virgilio, 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 applying the plan on selected activities, as appropriate.

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

## 2.2 Background

DSI-12

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.

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SECY-98-138

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

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

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

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

SECY-99-100

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

> Part 1 - Define regulatory application areas in which risk assessment methods can play a role in NRC's decision-making process. Group the areas by regulated use (e.g., fuel fabrication) and within each use by regulatory application (e.g., graded quality assurance).
>
> Part 2 - Evaluate the current considerations underlying the application area to ensure that the existing approach is altered only after careful consideration. Factors to be considered include deterministic considerations (hazard, relative importance of human vs. equipment error, defense-in-depth, codes and standards); current risk considerations (e.g., use of performance assessment in geologic repository licensing); and institutional considerations (existing statutory requirements, Agreement State issues, and licensee circumstances).

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

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

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

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

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

Step 3 - Change regulatory approaches.

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

Step 5 - Develop or adapt risk-informed tools.

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

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

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).

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

SRM for SECY-99-100

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

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

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

NMSS is following a three-phase plan to implement the framework described in SECY-99-100. The first two phases address the first step in the framework implementation process described in SECY-99-100 (identified above). The first phase focuses on developing a systematic approach for identifying candidate NMSS regulatory applications that may be amenable to increased use of risk information. The second phase focuses on applying the systematic approach developed through the first phase to identify the candidate NMSS regulatory applications. Finally, the third phase addresses Steps 2 through 5 of the SECY-99-100 framework implementation process. The third phase focuses on the actual modification of the identified regulatory applications to make them more risk-informed. The three phases are shown in Figure 3. Each of these three phases is discussed below.

### 2.3.1 Phase 1

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

In August 1999, NMSS staff were identified and reassigned to form the NMSS Risk Task Group. The Risk Task Group reported to the director of NMSS, reflecting the priority the director places on increasing the use of risk information in the regulatory applications of NMSS. Also, the

director formed the NMSS Risk Steering Committee, composed of management at the division and office level . The NMSS Risk Steering Committee provides management and policy direction to the Risk Task Group as necessary.

Screening Considerations

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 considerations 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 considerations and their applications, and (2) solicit public input for the process of developing risk guidelines for nuclear materials and waste applications. The workshop included participation by representatives from NRC, the Environmental Protection Agency, the Department of Energy, the Occupational Safety and Health Administration, the Organization of Agreement States, the Health Physics Society, the Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. The consensus of the workshop participants was that a case study approach and iterative investigations would be useful for the following purposes: (1) to test the screening considerations, (2) to show how the application of risk information has affected or could affect a particular area of the regulatory process, and (3) to develop risk guideline parameters and a first draft of risk guidelines for each area. These are similar to the gaps in the NMSS foundation that should be addressed to support risk-informing regulatory applications, as identified by staff in SECY-98-138.

Based on feedback received from stakeholders, the Risk Task Group, in consultation with the Risk Steering Committee, finalized the draft set of screening considerations for identifying NMSS regulatory applications amenable to increased use of risk information. The first consideration addressed whether a benefit would be realized from modifying a regulatory approach, based on the assessment of agency strategic performance goals. The remaining three considerations addressed technical feasibility, implementation costs, and other factors that could negate the potential benefits of, or significantly hinder, modifying the regulatory approach.

Case Studies

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

The Risk Task Group began the case studies in November 2000. The following case study areas were selected to reflect the diversity of NMSS materials and waste regulatory applications: regulation of generally licensed and specifically licensed devices (gas chromatographs, fixed gauges and static eliminators), decommissioning of the Trojan reactor site under the 10 CFR

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Part 20 license termination rule, transportation of the Trojan reactor vessel, regulation of uranium recovery facilities, certification of the Paducah gaseous diffusion plant, and licensing of the Idaho National Engineering and Environmental Laboratory independent spent fuel storage installation.

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

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

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

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

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

<u>Specific Risk-Informed Activities</u>

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

staff who were involved in the case studies and the development of the screening criteria and risk metrics and goals.

NMSS Risk Training

Also during Phase I, NMSS began to develop a training program addressing the use of risk information in materials and waste regulatory applications. The need for this training program was identified in SECY-98-138. NMSS developed a three-tier program, reflecting the depth and complexity of the course content. The Tier I and Tier II courses provide training on the general relevance of risk information and risk assessment methods in the Materials and Waste arenas to management and administrative and technical staff. Tier III courses provide training on specific aspects of risk assessment, management, and communication. Tier III training needs are identified through interaction with the NMSS division-level management. NMSS developed and began offering Tier I and Tier II courses in 2000. The targeted milestone of having at least 90% of staff complete Tier I and Tier II training was met. The specialized Tier III courses were developed and offered in 2001 and designated staff have completed the courses.

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

### 2.3.2 Phase 2

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

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

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

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### 2.3.3 Phase 3

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

NMSS has been actively managing risk-informed activities on a case-by-case basis, prior to and concurrent with the Phase 1 through 3 activities. Phase 2 compiled the completed and ongoing activities potential for risk-informing future activities. Because an approach has been developed for risk-informing the Materials and Waste Safety arenas, the Risk Task Group, and any associated developmental activities, were phased out at the end of FY 2004. NMSS will continue with Phase 3 by accumulating knowledge and experience on implementing a risk-informed approach, including trial applications of a systematic decision-making process.

### 2.3.4 Prioritization of Materials and Waste Safety RIRIP Implementation Activities

In accordance with the Commission's direction in the January 4, 2001, SRM on the October 2000 version of the RIRIP, the priority rating is listed under each implementation activity. A common prioritization scheme has been developed by the offices and is being used for the development of the 2006 budget. Currently, staff activities are prioritized as they relate to maintaining safety; improving effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence.

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

## 2.4. Description of Current Initiatives and Activities

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

<u>Nuclear Material Safety Arena</u>

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

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

MS-EER1-5 Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium

MS-EER1-6 Systematic Decision-Making Process Development

MS-EER2-1 Multi-phase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations)

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

MS-MS2-1 Materials Licensing Guidance Consolidation and Revision

MS-MS2-3 Implementation of Part 70 Revision

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

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

Nuclear Waste Safety Arena

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

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

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

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 3. Three-Phase Plan for Risk-Informing the Materials and Waste Safety Arenas**

**Phase 1**

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

**Phase 2**

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

**Phase 3**

Ongoing implementation of specific risk-informed initiatives and activities

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MS-EER1-1 Materials Safety Arena

**Implementation Activity:** **Developing a Framework for Incorporating Risk Information in the NMSS Regulatory Process**
(Lead Organization: NMSS/RTG)

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

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

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

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

- development of draft risk guidelines (joint effort with RES, expected to be completed by the end of FY 2004)
- development of proposed systematic decision-making process (expected to be completed by the end of FY 2004)

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

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

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

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

**Primary Priority:** 8
**Secondary Priority:** 11

**Project Considerations:** The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts. Additionally, the case-study approach involved numerous public workshops to solicit stakeholder input, in an enhanced participatory process. Also, in FY02 RES and RTG initiated a joint effort to continue development of risk guidelines and other tools, guidance, and data that may be need to risk-inform materials and waste regulatory processes and this collaboration continues through FY04.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Develop revised draft Risk Guidelines Report | June 2004 | | September 2004 |
| Develop revised draft systematic decision-making process guidelines | June 2004 | | September 2004 |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**

| Task | 2000 | | 2001 | | 2002 | | 2003 | | 2004 | | 2005 | | 2006 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Half 1 | Half 2 | Half 1 | Half 2 | Half 1 | Half 2 | Half 1 | Half 2 | Half 1 | Half 2 | Half 1 | Half 2 | Half 1 |
| Develop revised draft Risk Guidelines Report | | | | | | | | | | ♦ | | | |
| Develop revised draft systematic decision-making process guidelines | | | | | | | | | | ♦ | | | |

MS-EER1-4 Materials Safety Arena

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

(Lead Organization: NMSS/RTG and RES/PRAB)

***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)*

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

Furthermore, NMSS is developing a systematic decision-making process (see MS-EER1-6) for materials and waste applications. Risk guidelines would be a vital input to such decision-making process. Draft Revision 0 of the risk guidelines document was completed in April 2003. Revision 1 of the same document was completed in September 2003, followed by the Rev. 2 of the risk guidelines document in January 2004. The development of the risk guidelines was completed at the end of FY 2004. Beginning in FY 2005, NMSS intends to advance into the trial use phase where the applicability of proposed risk guidelines will be tested in various real-life NMSS applications.

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

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

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

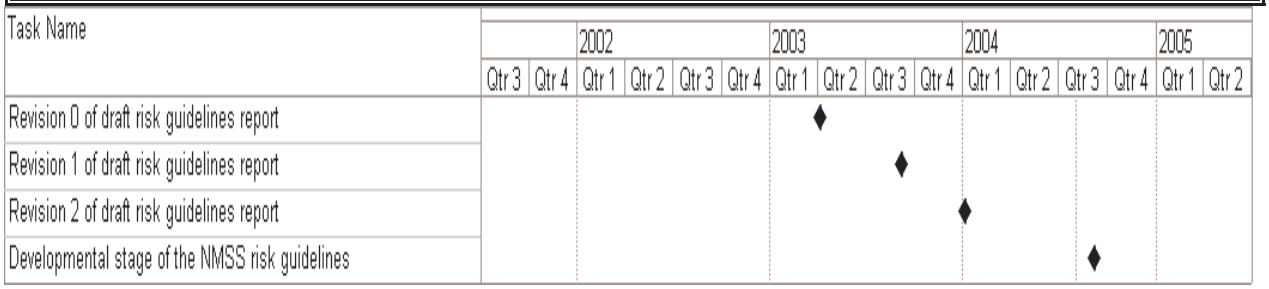
***Strategy 3:*** *Use sound science and state-of-the-art methods to establish risk-informed and, where appropriate, performance-based regulations.*

**Primary Priority:** 8
**Secondary Priority:** 11

**Project Considerations:** The NMSS RTG has developed a communications plan to support the development of the draft risk guidelines. In accordance with the SRM-SECY-99-100, the risk guidelines have been developed through an enhanced participatory process. RTG has conducted several pilot studies to test the applicability of the draft risk guidelines as part of the overall systematic decision-making process development.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Revision 0 of draft risk guidelines report | April 2003 | | April 2003 |
| Revision 1 of draft risk guidelines report | September 2003 | | September 2003 |
| Revision 2 of draft risk guidelines report | January 2004 | | January 2004 |
| Developmental stage of the NMSS risk guidelines | September 2004 | | September 2004 |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-EER1-5 Materials Safety Arena

**Implementation Activity:** **Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium**
(Lead Organization: NMSS/IMNS/RGB)

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

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

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

The Commission issued Staff Requirements Memorandum (SRM) on October 9, 2003 for this SECY paper. The Commission approved and disapproved in part the staff's recommendation. The Commission does not want the staff to continue to pursue legislation at this time, given they do not believe legislation will be approved by Congress. However, the Commission does want the staff to continue, on a low priority, to gauge the level of support with other Federal agencies and the States, as well as explore other possible approaches to achieving the goal of rationally treating these materials.

Staff plans to solicit comments from the individual States and other impacted Federal agencies with specific questions regarding the approach discussed in the SECY paper. Once we have that information, staff can evaluate the level of support for the recommendations in the SECY paper and any possible alternatives to legislation.

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

***Strategy 6:*** *Minimize unnecessary regulatory or jurisdictional overlap.*

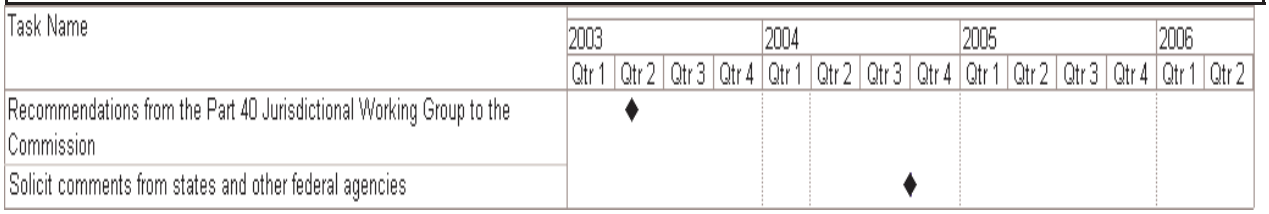
***Secondary FY 04-09 Strategic Plan Goal****: Ensure openness in our regulatory process.*

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

**Primary Priority:** 8
**Secondary Priority:** 15

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Recommendations from the Part 40 Jurisdictional Working Group to the Commission | June 2002 | March 2003 | May 2003 |
| Solicit comments from states and other federal agencies | September 2004 | December 2004 | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-EER1-6 Materials Safety Arena

**Implementation Activity: Systematic Decision-Making Process Development**

(Lead Organization: NMSS/RTG)

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

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

RTG, with support from the Brookhaven National Laboratory, is currently developing an integrated guidance document on the systematic decision-making process. The objective of this guidance document is to facilitate consistent and systematic use of risk insights in making regulatory decisions. Revision 0 of the draft systematic decision-making guidance document was completed in February 2004. Because risk guidelines (see MS-EER1-4) play a vital role in the overall decision-making process, it was decided to integrate the risk guidelines into the overall decision-making guidance document. Revision 0 of the integrated risk-informing guidance was completed in June 2004. Following the April briefings to ACNW, RTG incorporated feedback from the Committee in to the next revision of the integrated guidance document. The next version of the guidance document is expected to be completed by the end of FY 2004 when the developmental stage of the integrated systematic decision-making process guidance document is concluded. Beginning in FY 2005, NMSS will move into the trial phase where the systematic decision-making process will be tested through various NMSS applications.

In an effort to ensure the proposed decision-making algorithms are appropriate for NMSS applications, RTG has conducted several pilot studies to test the guidance document during the developmental phase of the systematic decision-making process guidance document.

<u>IMNS Pilot Study</u>
The subject of this pilot study relates to the regulatory requirements associated with the control and accountability of chemical agent detectors and monitors used by the U.S. Army. The large number of detectors/monitors (approximately 60,000) combined with the potential for continuing frequent loss of these devices (19 detectors have been lost within 1½ years) requires significant regulatory resources which may not be commensurate with the health significance resulted from the loss of these devices. Using this draft guidance document and the risk information contained in NUREG/CR-6642, RTG/IMNS generically addressed the risk significance of these devices and proposed some form of regulatory burden reduction, e.g., the use of enforcement discretion. This pilot study was completed in December 2003 to support staff's activities under SECY-03-0167, "Proposed License Amendment and Enforcement Action for the US Military."

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

Uranium Recovery Pilot Study

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

FCSS Pilot Study

With input from FCSS, a fourth pilot study in the area of how to balance different risks (e.g., fire with criticality) in license reviews is under way. This study is based on a previous NRC decision on approving a licensee's carbon dioxide fire suppression in a solvent extraction area due to criticality concerns. The goals of the study are to (1) identify risk insights staff used to balance different risks in license reviews, and (2) uncover gaps in the proposed systematic decision-making process logic. The pilot study is expected to be completed by the end of FY 2004.

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

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

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

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

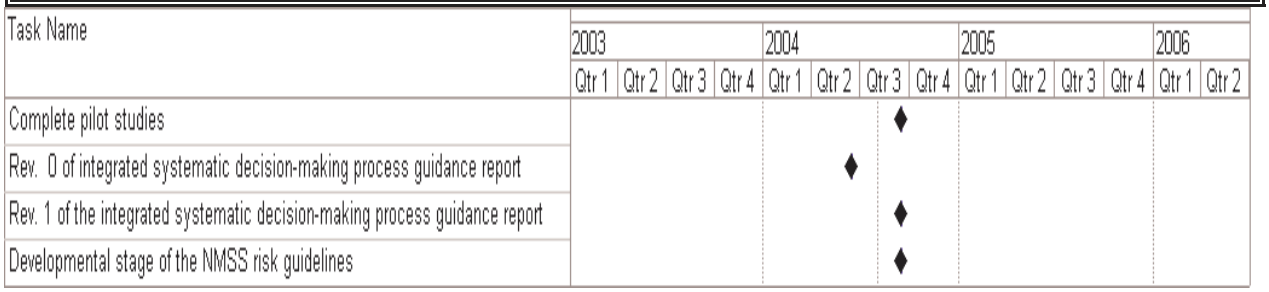
**Primary Priority:** 8
**Secondary Priority:** 11

MS-EER1-6 Materials Safety Arena

**Project Considerations:** Lessons learned from the pilot studies are being incorporated into the draft proposed systematic decision-making process guidance document. The draft guidance has been integrated with other previously developed guidance to provide a set of integrated guidance on a risk-informed approach for NMSS. Revision 0 of this integrated guidance was completed in June 2004. The next version of the guidance document is expected to be completed by the end of FY 2004.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Complete pilot studies | September 2004 | | |
| Rev. 0 of integrated systematic decision-making process guidance report | June 2004 | | June 2004 |
| Rev. 1 of the integrated systematic decision-making process guidance report | September 2004 | October 2004 | |
| Developmental stage of the NMSS risk guidelines | September 2004 | | September 2004 |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



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**Implementation Activity:** **Multi-phase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations)**
(Lead Organization: NMSS/IMNS/RGB)

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

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

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

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

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

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

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

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

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

**Primary Priority:** 8
**Secondary Priority:** 15

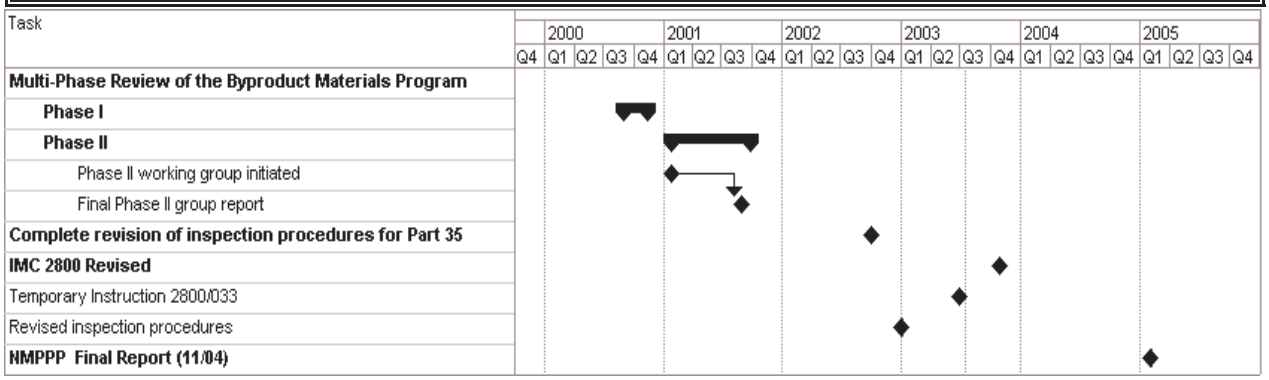
**Project Considerations:** The staff identified 20 recommendations from Phase I for specific changes to IMC 2800 and various inspection procedures. The Phase II review endorsed the majority of the Phase I recommendations. In addition, Phase II provided 24 recommendations for the broad, programmatic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

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

**Selected Major Milestones and Schedules**

| Major Milestones | Original Target Date | Revised Date | Completion Date |
|---|---|---|---|
| Final Phase I group report | November 2000 | | November 2000 |
| Final Phase II group report | August 2001 | | August 2001 |
| Complete revision of inspection procedures for Part 35 | Summer 2002 | | October 2002 |
| IMC 2800 Revised | July 2003 | September 2003 | October 2003 |
| 1. Temporary Instruction 2800/033 | April 2003 | July 2003 | July 2003 |
| 2. Revised inspection procedures | October 2002 | January 2003 | January 2003 |
| 3. NMPPP Final Report | November 2004 | | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



**Implementation Activity:** **Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements**
(Lead Organization: NMSS/IMNS/RGB)

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

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

The staff conducted a systematic reevaluation of the exemptions from licensing in Parts 30 and 40, which govern the use of byproduct and source materials. A major part of the effort was an assessment of potential and likely doses to workers and public under these exemptions. The assessment of doses associated with most of these exemptions was published as NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," June 2001. NUREG-1717 also includes dose assessments for certain devices currently used under a general or specific license that had been identified as candidates for use under exemption. The results of this study have been considered in the development of a rulemaking plan, "Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements," which was provided to the Commission in SECY-02-0196 (November 1, 2002). The rulemaking would revise the exemptions from licensing in Part 30 and the requirements for exempt distribution in Part 32 to make the controls more commensurate with the potential doses associated with the various exemptions. It would also establish one or more new exemptions to reduce regulatory burden related to the use of some products with low associated risks and make the regulations more flexible, user-friendly, and performance-based for requirements for distributors of generally licensed devices. Staff proposed that the results of the systematic reevaluation of the exemptions with respect to the regulation of source material would be addressed in a separate rulemaking addressed in SECY-01-0072, Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License, April 25, 2001. The staff is currently compiling supplement information to SECY-01-0072, as directed by the Commission. The SRM on SECY-02-0196 was issued on November 17, 2003. The Commission directed the staff to proceed with rulemaking, but disapproved the inclusion of certain issues in the rulemaking.

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

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

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

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

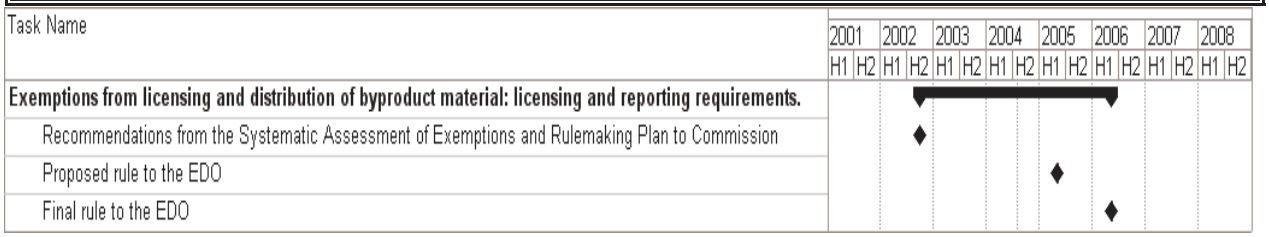
**Primary Priority:** 6
**Secondary Priority:** 8

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

The Working Group included members from NMSS, Region IV, OGC, OSTP, RES, and OE. It was expanded to include an Agreement State representative for the development of the proposed rule.

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-MS2-1 Materials Safety Arena

**Implementation Activity: Materials Licensing Guidance Consolidation and Revision**

(Lead Organization: NMSS/IMNS/RGB)

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

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

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

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

The following volumes of NUREG-1556 are scheduled for completion/review/revision in FY04 and FY05.

| | |
|---|---|
| Vol. 2 | Program-Specific Guidance About Radiography Licenses |
| Vol. 3 | Applications for Sealed Source and Device Evaluation and Registration |
| Vol. 8 | Exempt Distribution Licenses |
| Vol. 9 | Medical Use Licenses |
| Vol. 20 | Administrative Licensing Procedures |

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

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

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

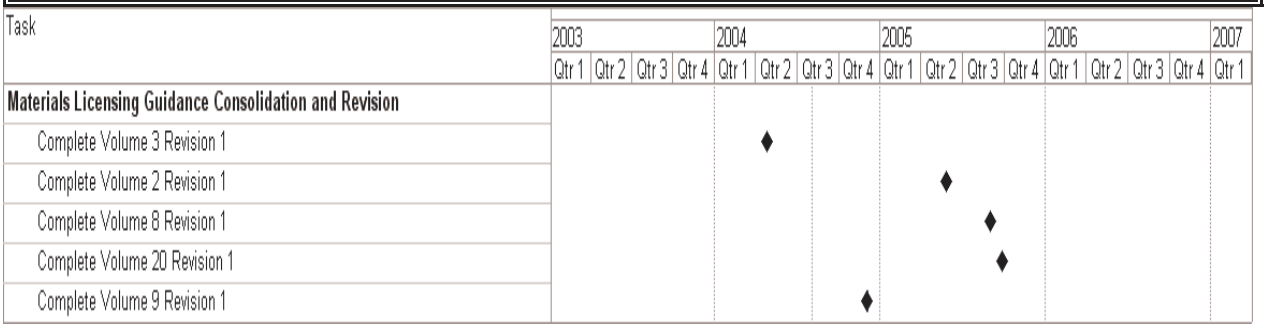
***Strategy 9:*** *Foster innovation at the NRC to improve systematically the NRC's regulatory programs.*

**Primary Priority:** 6
**Secondary Priority:** 8

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

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Complete Vol. 9 Revision 1 | December 2004 | | |
| Complete Vol. 3 Revision 1 | Summer 2003 | Winter 2004 | April 2004 |
| Complete Vol. 2 Revision 1 | Fall 2003 | Spring 2005 | |
| Complete Vol. 8 Revision 1 (Draft) | Summer 2005 | | |
| Complete Vol. 20 Revision 1 | Spring 2005 | Fall 2005 | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-MS2-3 Materials Safety Arena

**Implementation Activity:** **Implementation of Part 70 Revision**
(Lead Organization: NMSS/FCSS/TSG)

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

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

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

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

In December 2001, FCSS staff, along with the RTG and Part 70 stakeholders, finalized a Standard Review Plan to implement the requirements of Subpart H. This guidance document, which was published in March 2002, will assist the licensees in conducting ISAs and the staff in reviewing ISA documentation. In September 2003 and July of 2004, FCSS held ISA workshops with industry and the public to discuss implementation of the Part 70 Subpart H requirements, obtain industry comments and feedback from industry, and identify areas that needed additional study and/or guidance. During March to June 2004, FCSS also held six internal staff workshops to discuss ISA requirements, implementation, and issues. Interim staff guidance is being prepared for nine areas.

The staff began conducting ISA summary reviews in FY 2004 for individual amendment requests, for certain existing and new processes, and for a new centrifuge enrichment license application in FY 2004. The staff anticipates conducting reviews of site-wide ISA summaries in FY 2005 and FY 2006 for six operating uranium fuel fabrication facilities.

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

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

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

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

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

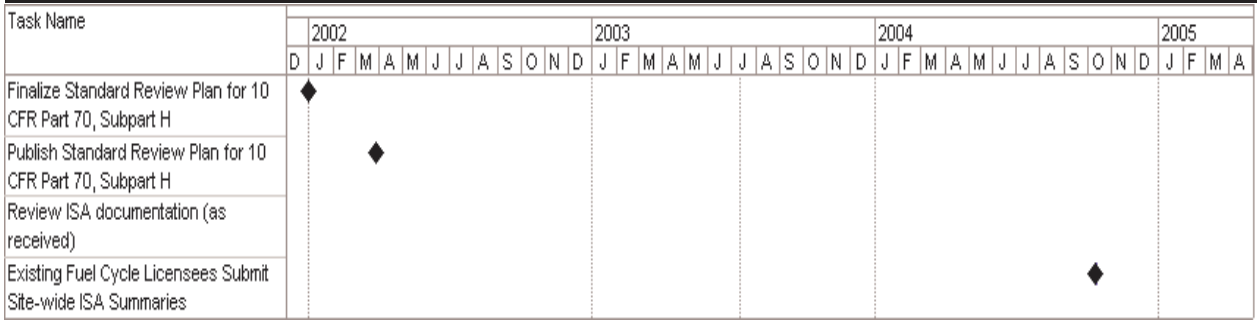
***Strategy 3:*** *Use performance-based regulation to minimize unnecessarily prescriptive requirements.*

**Primary Priority:** 6
**Secondary Priority:** 8

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

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-RB1-1 Materials Safety Arena

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

(Lead Organization: NMSS/IMNS/RGB)

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

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

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

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

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

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

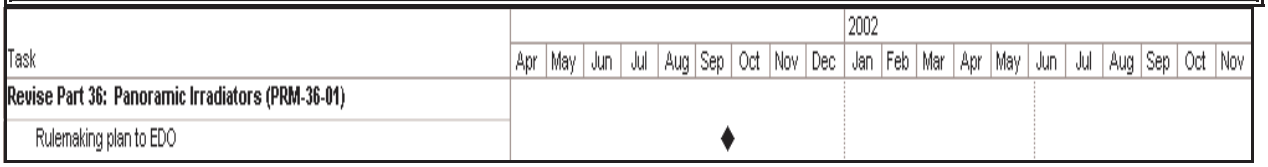
***Secondary FY 04-09 Strategic Plan Goal****: Ensure openness in our regulatory process.*

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

**Primary Priority:** 8
**Secondary Priority:** 15

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



MS-RB1-2 Materials Safety Arena

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

(Lead Organization: NMSS/IMNS/RGB)

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

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

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

PRM-34-05 requests deletion of the term "associated equipment" from 10 CFR Part 34. This would essentially remove associated equipment from consideration under 10 CFR 32.210(c) and 30.32(g), which require radiation safety evaluation and registration of sealed sources and devices. The staff sent a denial package to the Commission on November 13, 2002 (SECY-02-0202). The Commission approved the staff's recommendation to deny the petitioner's request subject to the staff revising guidance and inspection procedures and issuing a Regulatory Issues Summary to align NRC's guidance and practice with the applicable regulations. The Commission disapproved the draft FRN, letter to the petitioner, and letters to Congress; and directed the staff to consult with OGC in revising these documents. The revised denial package was submitted to the Commission on May 29, 2003 (SECY-03-0088). Denial of the petitioner's request was published in the Federal Register on July 15, 2003 (68 FR 41757). The staff is revising NUREG-1556, Volume 2, "Consolidated Guidance About Materials Licenses, Program-specific Guidance About Industrial Radiography Licenses" (August 1998), and Inspection Procedure 87121, "Industrial Radiography Programs" (December 2002), to incorporate the information contained in the denial notice.

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

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

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

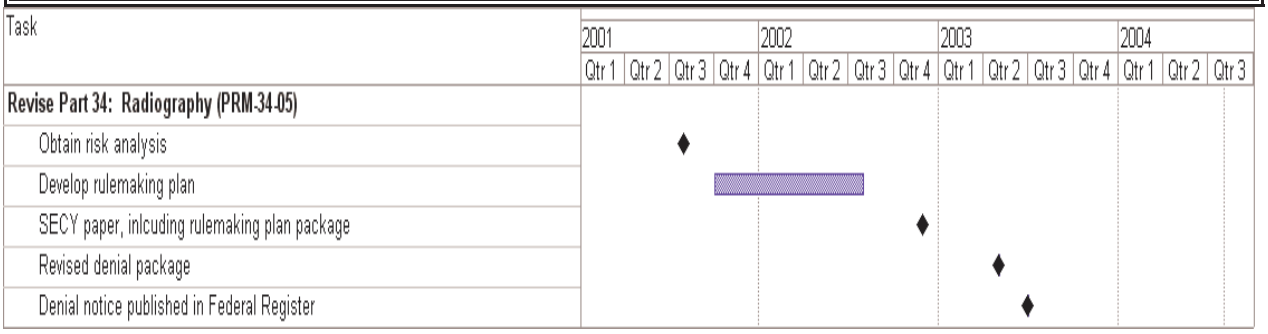
***Strategy 6:*** *Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory processes.*

**Primary Priority:** 8
**Secondary Priority:** 15

**Project Considerations:** The staff recommended that no rulemaking was necessary because the existing requirements achieve the intent of the petitioner's request to remove associated equipment from the sealed source and device evaluation process under § 32.210. The staff recommended that in order to reduce unnecessary regulatory burden for licensees, the NRC, and the Agreement States, NRC guidance should be revised to clarify that safety critical components of an industrial radiography system must be evaluated under the registration process for sealed sources and devices, but associated equipment need not be registered. The denial of the petition emphasized the risk-informed and more performance based approach.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Obtain risk analysis | July 2001 | | July 2001 |
| SECY Paper including denial package of PRM-34-05 | July 2002 | | November 2002 |
| Revised denial package (SECY-03-0088) | May 2003 | | May 2003 |
| Denial notice published in Federal Register | July 2003 | | July 2003 |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



WS-MS1-1 Waste Safety Arena

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

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

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

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

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

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

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

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

**Primary Priority:** 3
**Secondary Priority:** 1

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

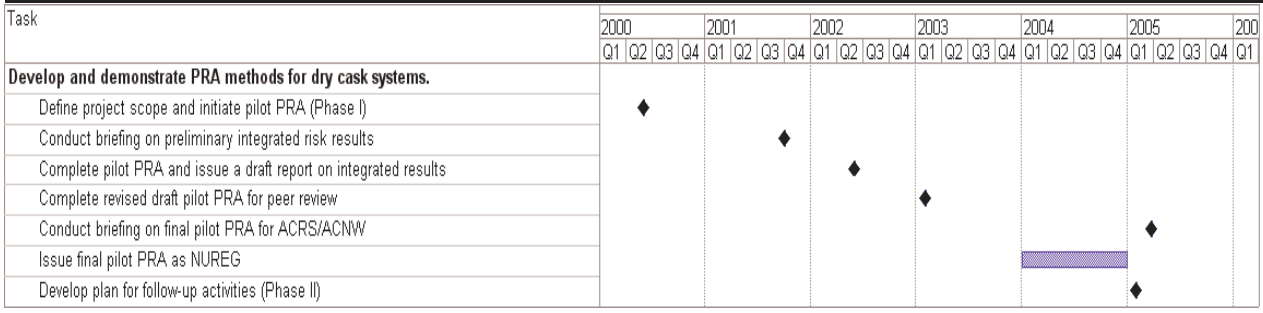
SFPO staff are taking PRA training presently offered through the TTC. Additionally, selected technical staff will be trained on the specific codes and methods employed in conducting this activity.

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

**Project Considerations for Phase II**: Under development.

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Define project scope and initiate pilot PRA (Phase I) | | | June 2000 |
| Conduct briefing on preliminary integrated risk results | November 2001 | | November 2001 |
| Complete pilot PRA and issue a draft report on integrated risk results | April 2002 | June 2002 | June 2002 |
| Complete revised draft pilot PRA for peer review | December 2002 | April 2003 | February 2003 |
| Conduct briefing on final pilot PRA for ACRS/ACNW | November 2002 | March 2005 | |
| Issue final pilot PRA as NUREG | 2005 | | |
| Develop plan for follow-up activities (Phase II) | February 2005 | TBD | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



**Implementation Activity:** **Incorporate Risk Information into the Decommissioning Regulatory Framework.** (Lead Organization: NMSS/DWM/DCB)

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

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

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

These assessments are a first step in a number of planned activities to be conducted during FY 2004-FY 2007 to implement all the LTR Analysis and Program Evaluation recommendations, including those identified above that will further risk inform the program. During FY 2004, the staff intends to complete two implementation plans that will identify the specific activities and schedules for each of the recommendations and thus define the specific work over the next few years. In general, for the LTR Analysis recommendations, in FY 2004, the staff plans to complete a Regulatory Issue Summary for our licensees and other stakeholders to describe the LTR issues, Commission approved recommendations, and general implementation schedule. In FY 2005 and FY 2006, staff will develop guidance for staff licensing reviews and inspections that will give further details about the risk informed approaches to institutional controls, exposure scenarios, and risk-ranking operating sites and activities that were described in SECY-03-0069. During this time of guidance development, however, the staff has begun and will continue to implement these new approaches at specific sites. The site-specific lessons learned are expected to enhance the guidance development process.

For the two Program Evaluation recommendations, in addition to preparing the implementation plan in FY 2004, the staff plans to develop training on the Consolidate Decommissioning Guidance and the risk-informed approach. Staff training and licensee workshops are expected to be ongoing during FY 2004 and thereafter and customized to address the needs of the

licensees and the stage of decommissioning. During FY 2004 and FY 2005, the staff also expects to develop and begin using a graded approach based on risk insights to improve the management of decommissioning resources.

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

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

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

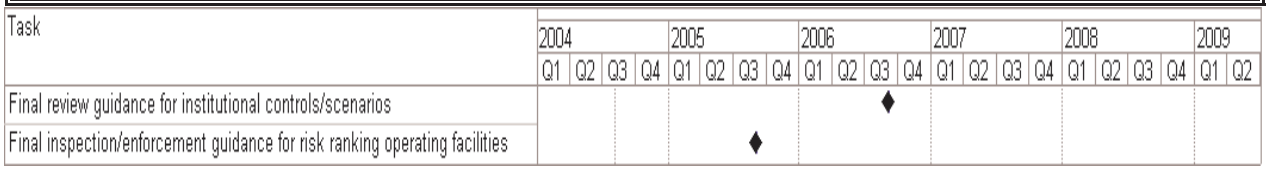
***Strategy 1:*** *Use state-of-the-art methods and risk insights to improve the effectiveness and realism of NRC actions.*

**Primary Priority:** 1
**Secondary Priority:** 2

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

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

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**



WS-MS1-3 Waste Safety Arena

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

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

The staff completed the risk insights initiative, and sent to the Commission the Risk Insights Baseline Report, in April 2004. The Risk Insights Baseline Report provides an overall, integrated perspective for evaluating the risk significance of repository issues and systems down to the subsystem level. The staff is using the risk insights baseline as a common reference as it conducts risk-informed issue resolution activities and develops a risk-informed Yucca Mountain inspection program. The staff intends to refine the risk insights baseline as risk information becomes available, and utilize the baseline in its review of a Yucca Mountain license application and other regulatory activities. In early 2005, the staff will complete a set of risk analyses, and will review and update the risk insights baseline, as appropriate.

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

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

***Secondary FY 04-09 Strategic Plan Goal****: Enhance the effectiveness and efficiency of agency management to better support NRC's Mission.*

***Strategy 2:*** *Improve the effectiveness of communications throughout the NRC.*

**Primary Priority:** 1
**Secondary Priority:** 5

**Project Considerations**: NRC's HLW program activities and milestones anticipated for FY 2005 may be affected by external factors, such as the pending submittal of a license application for a HLW repository by DOE in December 2004, and uncertainties associated with litigation of the EPA's radiation protection standards for Yucca Mountain (40 CFR Part 197).

| Selected Major Milestones and Schedules | | | |
|---|---|---|---|
| **Major Milestones** | **Original Target Date** | **Revised Date** | **Completion Date** |
| Develop Total-system Performance Assessment (TPA) code, Version 5.0 | September 2003 | | September 2003 |
| Develop pre-decisional Risk Insights Baseline Report | November 2003 | | December 2003 |
| Using risk insights, conduct independent assessments of the DOE program | December 2003 | | January 2004 |
| Provide Final Risk Insights Baseline Report to Commission | | | April 2004 |
| Conduct risk-informed issue resolution activities (agreements) using risk insights | Ongoing | | Ongoing |
| Develop Pre-Closure Safety Analysis (PCSA) Tool for evaluating preclosure risks | September 2004 | October 2004 | |
| Issue update of the consolidated Issue Resolution Status Report for issue closure using risk insights | September 2004 | October 2004 | |
| Develop HLW inspection procedures using risk insights (Complete 7 integrated inspection procedures) | September 2004 | December 2004 | |
| Complete risk analyses and update risk insights baseline | December 2004 | | |

**Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year**