Attachment 1

Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
October 2000

FOREWORD

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

> The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.
>
> PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.
>
> PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.
>
> The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgements on the need for proposing and backfitting new generic requirements on nuclear power plants licensees. The Commission also said -
>
> Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decision-making.

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

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

> To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the

> staff to develop a comprehensive strategy that includes but is not limited to objectives, goals, activities, and time frames for the transition to 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 the transition. This version of the implementation plan is the first complete version. The purpose of this plan is to integrate the Commission's risk-informing activities. This version also includes the supplementary material the Commission asked for last April.

The staff intends to solicit internal and public comments on this version of the plan. These comments will be reflected in the next semiannual version, which the staff plans to finish in May 2001 following updates to Office operating plans.

Part I - The Nuclear Regulatory Commission's (NRC) Transition to Risk-Informed Regulation

1. Relevance to Strategic Plan

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 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. The movement toward risk-informed regulation has indeed focused regulatory (and therefore licensee) attention on safety, reduced unnecessary regulatory burden, and made the regulatory process more effective and efficient. 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 implementing risk-informed regulation openly, giving the public and the nuclear industry clear and accurate information and a meaningful role in the process.

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

While the PRA policy statement and other risk-informed regulatory initiatives were being developed, the NRC also developed a strategic plan for accomplishing its mission. The strategic plan sets strategic and performance goals and strategies for four strategic arenas: Nuclear Reactor Safety, Nuclear Materials Safety, Nuclear Waste Safety, and International Nuclear Safety Support. The agency has established four performance goals for the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas: (1) to maintain safety and protect the environment and the common defense and security, (2) to increase public confidence, (3) to make NRC activities and decisions more effective, efficient, and

realistic, and (4) to reduce unnecessary regulatory burden. The strategic plan guides the agency's initiatives to support the transition to risk-informed regulation by defining strategic goals, performance goals and measures, and "strategies." The strategic plan strategies are general in nature. The RIRIP fills out some of the details, including –

- ongoing or planned activities to implement strategic plan strategies for risk-informed regulation
- draft criteria for risk-informing a program, practice, or requirement
- factors to consider in risk-informing a program, practice, or requirement
- relevance to performance-based regulation

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

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

As the Federal agency responsible for regulating the civilian applications of nuclear technology, the NRC licenses a wide range of activities, including nuclear power generation, nuclear materials disposal, transportation and storage, nuclear materials processing and fabrication, and industrial and medical applications. The staff has developed draft screening criteria for identifying regulatory activities that could benefit from risk information. The screening criteria define the agency's policy on risk-informing regulations. Accordingly, they constitute the agency's overall strategy for implementing the 1995 policy statement. The staff will revise the criteria as it gains experience in apply them.

The draft screening criteria (65FR174) will help in assessing whether risk-informing a regulatory requirement or practice would –

- resolve a safety concern
- make the NRC (or Agreement States) regulatory process more efficient, effective or realistic
- reduce unnecessary regulatory burden on the applicant or licensee
- help to effectively communicate a regulatory decision or situation
- rely on existing risk data and analytical models (or data and models that could be developed)
- have a net benefit
- not encounter factors that would preclude changing the regulatory approach and therefore limit the utility of implementing a risk-informed approach.

Part 2 of the RIRIP tells how to apply the screening criteria. Results of the preliminary screening (described in the safety arena chapters in Part 2) will be incorporated in the agency's planning, budgeting, and performance management process.

3. Factors to Consider in the Transition to Risk-Informed Regulation

The NRC mission is to protect the public health and safety in civilian applications of nuclear technology. Historically, the agency has used an effective, albeit often conservative, approach for regulatory decisions. To accomplish its mission, the agency has established a regulatory system which presumes that the public health and safety are adequately protected when licensees comply with regulations and other 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 the transition to risk-informed regulation will be to maintain an acceptable level of safety while (1) improving efficiency, effectiveness, and realism in agency decisions, practices, and processes, (2) increasing public confidence in the agency, and (3) reducing unnecessary regulatory burden on licensees.

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[1]. Risk assessment insights will make regulatory decisions more effective and efficient and reflect realism.

For uniformity, the following factors should be considered in risk-informing an agency requirement or practice.

Defense-in-Depth

Traditionally, the NRC has required defenses to prevent radionuclide releases, to mitigate releases, and to limit human exposures to releases. Generally, defense-in-depth requires successive compensatory measures to prevent radiation exposures and to prevent accidents or mitigate damage during a malfunction, an accident, or a natural event such as an earthquake or

[1]The appendix discusses issues to consider in applying these principles in risk-informed regulation. Part 2 of the plan describes implementation activities to resolve the issues.

a tornado. In mechanical systems, defense-in-depth is assured by redundancy and diversity of power sources and physical separation of mitigation systems. Likewise, exposure to radiation is limited by shielding, distance, and time. In risk-informing a requirement or practice, the number and nature of physical and functional barriers for ensuring defense-in-depth should be commensurate with the risk and the uncertainty of the defenses.

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

- Is defense-in-depth commensurate with the risk and uncertainty associated with the estimate of risk?
- Is a reasonable balance preserved among accident prevention, radiation exposure prevention, and consequence mitigation?
- Is there over-reliance on programmatic activities to compensate for design weaknesses?
- Is the 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 implementing 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, which assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur, 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.

In implementing 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

The agency has developed quantitative safety goals for nuclear reactors to determine “how safe is safe enough?” The agency uses these goals as benchmarks for calculated risk measures. The Commission has directed the staff to develop materials safety goals similar to the NRC’s reactor safety goals.

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

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

Other considerations for establishing quantitative safety goals are discussed in Appendix A.

Performance-Based Implementation

The agency has defined a performance-based requirement as one that relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. SECY-00-0191 lists high-level guidelines that are intended to promote the use of a performance-based regulatory framework throughout the agency. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn can result in a more efficient and effective regulatory process.

Having established the feasibility of the guidelines, the staff plans to develop implementing guidance to incorporate the guidelines into internal NRC procedures and to apply the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities. Risk-informed regulation should incorporate performance measures whenever possible. Conversely, performance-based regulations should be risk-informed when possible. Figure 1 in the Appendix illustrates risk-informed and performance-based approaches.

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

- Are there measurable or calculable parameters and criteria for judging the licensee’s or the system’s performance?
- Can the risk-informed change be made as a performance-based change?

Voluntary Alternatives versus Mandatory Requirements

The Commission has allowed reactor licensees to voluntarily implement risk-informed regulation. Thus, licensees may continue to operate under current requirements, or they may adopt a risk-informed approach. However, 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?
- Should the regulation offer licensees alternative requirements?

- If staff practices are risk informed, are they mandatory or voluntary?

Selective Implementation

The issue is whether licensees that wish to use risk-informed options may selectively implement risk-informed requirements or must implement them all. Currently, selective implementation is decided on a case-by-case basis.

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

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

Regulatory Oversight Process

The staff should follow the agency's regulatory oversight process in risk-informing requirements. Oversight can consist of inspection, assessment (e.g., through use of performance indicators), or enforcement. The staff should ask of every risk-informed regulation –

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

4. Communication Plans

The agency recognizes that it must keep its staff, the public, and the nuclear industry informed about its risk-informed regulatory activities. Part 2 of this plan lists milestones for soliciting input and feedback on certain regulatory initiatives in the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas. Part 3 describes the agency's plans for communicating the plan and obtaining input and feedback on it.

The staff guidance will be revised to incorporate advice on implementing risk-informed regulations (and performance-based regulations, as applicable) and explain the agency's PRA policy statement. For example, the management directive on the rulemaking process may be revised to describe the screening criteria for risk-informing regulations. Likewise, the charter of the agency's Committee for the Review of Generic Requirements (CRGR) may be revised to include reviewing criteria for risk-informing regulations.

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. Additional training has been given on certain risk-informed regulatory initiatives, such as the training reactor inspectors were given on the revised reactor oversight process. In the Nuclear Materials Safety and Nuclear Waste Safety arenas, the NRC's Office of Human Resources is identifying, developing, and implementing staff training to ensure that the staff is fully prepared to effectively implement risk-informed regulation. Details of the agency's training program are given in Part 3 of this plan.

6. Success Measures

The performance goals in the NRC strategic plan use performance-based measures to determine whether the NRC is achieving its strategic goals. In 1999 the agency promised to include strategic and performance goals with performance-based measures in the performance plan and to describe how the agency programs and activities are linked to the strategic plan goals, measures, and strategies. Consequently, one function of the RIRIP is to identify risk-informed regulation milestones to be included in the performance plan. The staff is currently working to develop criteria for judging whether the transition to risk-informed regulation is proceeding in a successful manner but expects to develop the criteria by the end of calendar year 2000.

7. Organization of the RIRIP

Safety Arena Chapters

Part 2 of the plan describes the staff's activities for the risk-informed regulation transition. The activities are described as implementing strategic plan strategies. Thus Part 2 is organized like the Commission's strategic plan, with chapters on the Nuclear Reactor Safety arena, Nuclear Materials Safety arena, and Nuclear Waste Safety arena. Each chapter is organized around the strategic plan strategies relevant to risk-informed regulation in that arena. The implementation activities for each strategy are described, significant milestones are listed, and milestones schedules are noted. Progress in completing established milestones is also discussed. Tables 1 through 3 are summary lists of the implementation activities planned within each safety arena.

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.

Corporate Management Chapters

Part 3 of the plan describes the training program for giving the agency's staff the knowledge and skills needed to implement risk-informed regulation. Part 3 also describes the

management strategies for ensuring effective communications among the NRC staff during the transition to risk-informed regulation.

Table 1. Nuclear Reactor Safety Arena Implementation Activities

Reactor Safety	Licensing	Regulatory Oversight
RSMS1-1	Oversight framework	Oversight framework
RSMS1-2		Inspection program
RSMS1-3		Performance indicators
RSMS1-4		Assessment process
RSMS1-5		Enforcement program
RSMS1-6		Improve oversight process
RSMS3-1		Risk-based performance indicators
RSMS3-2		Analyze performance indicators
RSMS3-3	Plant reliability studies	Plant reliability studies
RSMS3-4		Accident sequence precursors
RSMS3-5	System reliability studies	System reliability studies
RSMS3-6	IPEEE	IPEEE
RSMS5-1	Risk-informed licensing guidance	
RSMS8-1	RI Part 50 (Option 2)	
RSMS8-2	RI Part 50 (Option 3)	
RSMS8-3	Standard TS	
RSMS8-4	Fire protection	
RSMS8-5	Safeguards	
RSMS8-6	Reactor pressure vessel integrity	
RSEER1-1	Advanced reactors	
RSEER1-2	Standards	
RSEER1-3	Methods development	
RSEER1-4	Analytical tools	Analytical tools
RSEER1-5	International cooperation	International cooperation
RSEER1-6	Regulatory effectiveness	

Table 2. Nuclear Materials Safety Arena Implementation Activities

Materials Safety	Licensing	Regulatory Oversight
MSMS1-1	Identify and prioritize “candidate” regulations for risk-informing	Identify and prioritize candidates for RIR
MSMS1-2	Analyze Petition for Rulemaking (PRM) 36-1 (10 CFR 36.65 irradiator)	Revise inspection guidance for irradiators
MSMS1-3	Revise 10 CFR Part 35 (medical)	
MSMS1-4	Amend 10 CFR Part 70 PRM-70-7 (critical mass of special nuclear materials)	
MSMS1-5	Consolidate risk-informed on irradiators, limited scope, broad scope, radiopharmacy	
MSMS1-6		(1) Revise the nuclear fuel cycle facility safety inspection program (safety focus, baseline inspections) (2) Develop risk-informed enforcement actions for fuel cycle facilities
MSMS3-1		Streamline inspection and enforcement of materials licensees
MSEER1-1	Develop dose estimates to support Clearance Rule	Develop radiation protection standards and guidance for byproduct materials and guidance on sewer treatment facilities

Table 3. Nuclear Waste Safety Arena Implementation Activities

Waste Safety	Licensing	Regulatory Oversight
WSMS1-1	Study spent fuel cask responses to severe transportation accidents	Study spent fuel cask responses to severe transportation accidents
WSMS1-2	PRA of spent fuel dry storage cask	PRA of spent fuel dry storage cask
WSMS1-3	Risk-informed review of geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste	
WSMS1-4	Revise 10 CFR 72.102 (graded approach to seismic design of dry cask storage)	
WSMS1-5	Reactor decommissioning rulemaking	
WSMS1-6	Risk-informed review of independent spent fuel storage installation	
WSMS1-7		Incorporate risk information into the decommissioning regulatory framework
WSMS4-1	Identify issues most important to repository safety	Identify issues most important to repository safety
WSMS4-2	Resolve issues most important to repository safety	Resolve issues most important to repository safety