June 11, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: RISK-INFORMED, PERFORMANCE-BASED AND RISK-INFORMED, LESS-PRESCRIPTIVE REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

PURPOSE:

To inform the Commission of the staff's approach for increasing the use of risk-informed, performance-based (RIPB) regulation in the Office of Nuclear Material Safety and Safeguards (NMSS). Also, to inform the Commission that a framework for applying probabilistic risk assessment (PRA) to nuclear material uses is likely to differ from the framework for applying PRA to reactor regulation, because of important differences between nuclear material uses and reactors and between their respective licensee communities.

SUMMARY:

This paper addresses the direction in the SRM of April 15, 1997 that was specifically concerned with the use of RIPB regulatory approaches for nuclear material uses and radioactive waste disposal. To establish an overall context, it starts with the definitions and discussion of regulatory approaches in the staff discussion of RIPB regulation (forwarded to the Commissioners' assistants by James Blaha on May 4, 1998). This is followed by consideration of (1) the need for a framework for the application of RIPB approaches to the regulation of nuclear materials uses and (2) the applicability of the SECY-95-280 framework for reactors to nuclear materials regulation. Based on these considerations, the paper concludes that a framework for applying RIPB to nuclear materials uses is timely and that such a framework likely will differ from the reactor framework. Finally, the paper discusses various issues that will need to be addressed before developing a nuclear materials framework and presents the staff's plan for developing such a framework.

CONTACTS: Margaret V. Federline, NMSS/DWM
(301) 415-6708

Seth M. Coplan, NMSS/DWM
(301) 415-5873

BACKGROUND:

In the Commission's Strategic Assessment and Rebaselining initiative, one of the Direction- Setting Issues (DSIs) was Risk-Informed, Performance-Based Regulation (DSI-12). The Commission expressed its view on the matters that were discussed in the DSI-12 issue paper in a Staff Requirements Memorandum (SRM) issued on April 15, 1997. Regarding NMSS, the SRM states:

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.

The application of risk-analysis methods to nuclear materials uses is guided by the PRA Policy Statement and the PRA Implementation Plan; however, as the SRM notes, a framework for applying such methods to nuclear materials has not been developed. The framework for reactors that is referenced in the SRM was transmitted to the Commission in November 1995. Since that time, the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Regulatory Research (RES) have made substantial progress toward completing the six-step process that was envisioned for implementing the framework. In particular, the staff issued draft NUREG-1602, five draft Regulatory Guides, and related draft Standard Review Plans for public comment. A proposed final revision of the general guide was transmitted to the Commission by SECY-98-015 and approved by the SRM of May 21, 1998. Proposed final revisions of the guides on inservice testing, technical specifications, and graded quality assurance were transmitted to the Commission by SECY-98-067.

DISCUSSION:

It is useful first to establish a common understanding of RIPB and other regulatory approaches. The definitions and discussion in the following eight paragraphs have been excerpted from the staff discussion of RIPB regulation.

The triplet definition of risk[1] is used in this paper because it defines risk at a fundamental level that can be applied to the entire range of activities involving NRC licensed use of Atomic Energy Act (AEA) materials. The risk triplet definition takes the view that when one asks, "What is the risk?" one is really asking three questions: "What can go wrong?" "How likely is it?" and "What are the consequences?" A risk assessment is a systematic method for addressing the risk triplet as it relates to the performance of a particular system (which may include a human component) to understand likely outcomes, sensitivities, areas of importance, system interactions and areas of uncertainty. From this assessment the important scenarios can be identified.

All safety regulation ultimately is concerned with risk and addresses the three questions of the risk triplet. In practice, NRC addresses these three questions through the body of regulations, guidance, and license conditions that it uses to regulate the many activities under its jurisdiction. The current body of regulations, guidance and license conditions is based largely on a "deterministic" approach. As described in the PRA Policy Statement, the deterministic approach to regulation establishes requirements for engineering margin and for quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist and establishes a specific set of design basis events (i.e., what can go wrong?). The deterministic approach involves implied, but unquantified, elements of probability in the selection of the specific accidents to be analyzed as design basis events. It then requires that the design include safety systems capable of preventing and/or mitigating the consequences (i.e., what are the consequences?) of those design basis events in order to protect public health and safety. Thus, a deterministic approach explicitly addresses only two questions of the risk triplet.

A probabilistic approach to regulation (also described in the PRA Policy Statement) considers risk (i.e., all three questions) in a more coherent and complete manner. The probabilistic approach explicitly addresses a broad spectrum of initiating events and their event frequency. It then analyzes the consequences of those event scenarios and weights the consequences by the frequency, thus giving a measure of risk.

The term "risk insights", as used here, refers to the results and findings that come from risk assessments. The most fundamental results relate directly to public health effects, as in the Commission's Safety Goals. For specific applications the results and findings may take other forms. For example, for reactors these include such things as identification of dominant accident sequences, estimates of core damage frequency (CDF)(2) and large early release frequency (LERF)(3), and importance measures of structures, systems, and components. In other areas of NRC regulation, these include risk curves(4) for disposal facilities for radioactive wastes, frequency of accidental smelting of sealed sources at steel mills, frequency of occupational exposures, predicted dose from decommissioned sites and many others.

A "risk-informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. A "risk-informed" approach enhances the traditional approach by: (a) allowing explicit consideration of a broader set of potential challenges to safety, (b) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (c) facilitating consideration of a broader set of resources to defend against these challenges, (d) explicitly identifying and quantifying sources of uncertainty in the analysis, and (e) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions. Where appropriate, a risk-informed regulatory approach can also be used to reduce unnecessary conservatism in deterministic approaches, or can be used to identify areas with insufficient conservatism and provide the bases for additional requirements or regulatory actions.

A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including licensee, performance against clearly defined, objective criteria, (2) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (3) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including reference to regulatory guidance adopted by the licensee. This regulatory approach is not new to the NRC. The Commission previously has approved performance-based approaches in 10 CFR Parts 20, 60, and 61. In particular, the Commission weighed the relative merits of prescriptive and performance-based regulatory approaches in issuing 10 CFR Part 60.

A performance-based approach can be implemented without the use of risk assessment. Such an approach would require that objective performance criteria be based on deterministic safety analysis and performance history. This approach would still provide flexibility to the licensee in determining how to meet the performance criteria. Establishing objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible.

A risk-informed, performance-based approach to regulatory decision-making combines the "risk-informed" and "performance-based" elements discussed above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria based upon risk insights for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, and (4) focus on the results as the primary basis of regulatory decision-making.

Starting in the mid-1970s, NMSS has developed and used various risk-analysis methods to support its existing or potential risk-informed regulatory approaches. For example, the staff has been a developer of performance assessment (PA) methodology for geologic disposal of high-level radioactive waste and land disposal of low-level radioactive waste. NMSS' current efforts in PA were discussed with the Commission in a May 1997 briefing. Similarly, the staff made early efforts to apply PRA methods to gain a better understanding of transportation risks, most notably, the "Transportation Modal Study" (NUREG/CR-4829). More recently, the staff has

undertaken the new efforts that are described in Attachment 1 (a discussion of considerations related to the use of RIPB regulation in NMSS) to use or develop risk-analysis methods to satisfy a variety of purposes and objectives. For example, a recent paper, SECY-97-137, concerning proposed revision of 10 CFR Part 70, discusses the use of integrated safety analyses (ISAs) in the regulation of fuel cycle facilities. In identifying and conducting these efforts, the staff's approach has been appropriately flexible and developmental. However, as the number of staff efforts has grown and as resources become more scarce, there is an added need for policy and technical consistency and assurance that resources are being used judiciously. Accordingly, development of a framework for applying PRA to nuclear materials uses is timely.

As described in SECY-95-280, the framework for use of PRA in reactor regulation is a four part, general structure to ensure consistent and appropriate application of PRA methods. The staff's goal is to develop a framework for applying risk-analysis methods to nuclear material uses that will be consistent with the purpose and principles of the reactor framework. To assure that such a framework would address the issues of greatest concern to the nuclear materials regulatory program, the staff considered several assumptions that are implicit in the reactor framework in the context of NMSS-regulated licensees and activities. These considerations are discussed in some detail in Attachment 1, as is the staff's conclusion that a framework for applying risk-analysis methods to nuclear materials uses likely will differ from the reactor framework in some of its specifics. Most importantly, the staff concluded that, in a framework for nuclear materials: (1) PRA may be applicable to only a few specific uses and, for most licensed uses, other system analysis methods that address the three risk questions will need to be considered instead; (2) integrating deterministic and probabilistic considerations will likely be a much less important issue, and other issues, such as relating the level of analytic sophistication to the risk associated with specific nuclear materials uses, will likely be much more important in the materials framework; and (3) a broader range of licensee and regulator circumstances will need to be addressed. In brief, the staff reached these conclusions in consideration of substantial differences between: (1) nuclear reactors and the approximately 40 activities, systems, and devices that use nuclear materials; (2) reactor licensees and the roughly 20,000 nuclear materials licensees; and (3) the reactor regulatory program and the materials regulatory program, including its Agreement State program. The staff's specific considerations are discussed in Attachment 1.

Before and while developing a framework for nuclear material uses, the staff would need to address several other essential points. More specifically, when the framework for applying PRA in reactor regulation was developed, a sound and extensive foundation of pertinent experience and policy already had been established. For the nuclear materials regulatory program, some elements of a foundation are in place, but there are important gaps. These include gaps in: (1) experience with strengths and limitations of potentially useful analytic methods; (2) knowledge of which of these methods may be applied usefully to a specific nuclear materials use; (3) established policy (e.g., a safety goal policy statement has been issued for reactors, but no similar statement has been issued for nuclear materials uses); and (4) staff training programs.

The staff would address some gaps in its experience and knowledge through the projects that are part of the PRA Implementation Plan. These projects are intended, in part, to test or develop system analysis methods for certain nuclear material uses. The staff will address the policy gaps by making recommendations to the Commission about: (1) whether a safety goal policy statement for nuclear materials use should be developed; and (2) criteria for determining whether RIPB regulation of a given materials use is appropriate. A safety goal policy statement would seem to be a valuable, if not essential, element of RIPB regulation; however, its development would be quite difficult because permissible risk levels of nuclear materials uses vary and stem, at times, from several conflicting statutes and other standard-setting sources. Criteria for determining whether a particular application of RIPB regulation would be appropriate must strike a difficult balance between several factors. Specifically, nuclear materials licensees have evinced no groundswell of interest in extending RIPB regulation-perhaps because many of them lack the necessary technical and economic resources. Also, the staff is not aware of any inadequacies in protection of public health and safety that would require substantial change in its current regulatory approaches; however, the staff recognizes, too, that the individual plant examination program revealed important potential vulnerabilities in a number of licensed reactors. Finally, with respect to training, the staff plans to determine what training will be needed to implement the framework and develop an appropriate program.

In developing the framework itself, the staff first would need to consider carefully the current NRC regulatory approaches to identify any fundamental regulatory principles (e.g., defense-in-depth) that the framework should preserve. This was an important step in developing the reactor framework. Once such principles were identified, in analogy with the reactor framework, the staff would develop appropriate "parts" of the framework and implementation steps. The staff would use as much of the reactor framework as is practicable. Because of the special concerns of the Agreement States, the staff would work closely with them throughout development of the framework. Also, the substantial progress made by NRR and RES toward implementing the reactor framework should provide useful insights for developing a framework for nuclear materials. Accordingly, the staff will coordinate its development effort with the Interoffice PRA Coordinating Committee. The staff will start with a scoping effort in which it will (1) complete a preliminary association of appropriate risk assessment methods with regulated uses of nuclear materials and (2) as appropriate for each regulated use and in coordination with the Agreement States, identify how these associated risk assessment methods can best be used in a risk-informed regulatory framework for materials. The staff believes that this effort is an essential first step toward developing a framework and determining the ultimate feasibility of completing a framework, given NRC's resource constraints. The staff's plan and its basis are discussed more fully in Attachment 1. A schedule is provided as Attachment A to Attachment 1. In Attachment B to Attachment 1, the staff reexamines the applicability of its RIPB approaches. Consistent with its belief that experience in system analysis methods is essential to successful implementation of RIPB approaches in the nuclear materials area, the staff broadened the Commission's request to include all the Task 4 and 5 activities of the PRA Implementation Plan. The staff concludes that these approaches should be continued as resources permit. The SRM also requested that the staff review the basis for nuclear materials regulations and processes, and identify and prioritize those areas that are either now, or could be made, amenable to RIPB approaches with minimal additional staff effort/resources. In Attachment 2 (a preliminary review of NMSS' regulations and processes), the staff surveys the nature of the nuclear materials regulations and processes. The staff believes that a full response to the Commission's request must await completion of several steps in its plan to develop a framework and will provide that response upon completion of those steps.

RESOURCES:

The start of several major rulemakings, in the nuclear materials area, is planned during the next three years. The staff believes that it is important to start the tasks now that will help to determine which nuclear material uses are potential candidates for a RIPB approach and which rulemakings would be affected in turn. The staff's plan to develop a framework for nuclear material uses would begin with a scoping phase that would be completed in December 1998 and would, in part, evaluate the resources needed to complete development of and implement the framework. The scoping phase would require a 1.5 FTE effort and no contractor assistance. No resources have been budgeted for the effort described in this paper. All nuclear-materials-related rulemakings have been transferred from the RES to NMSS along with the resources budgeted for them. NMSS is assessing resource requirements for transferred rulemakings, including an assessment of status and of residual actions required. After making such an assessment, NMSS would be in a position to advise the Commission of any necessary deferrals or cancellations to accommodate the scoping effort described in this paper.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections to its issuance. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. There is no information technology impact that would result directly from this paper.

L. Joseph Callan
Executive Director for Operations

Attachments: As stated

ATTACHMENT 1

RISK-INFORMED, PERFORMANCE-BASED AND RISK-INFORMED, LESS-PRESCRIPTIVE REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

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1. INTRODUCTION AND BACKGROUND

In the Commission's Strategic Assessment and Rebaselining initiative, one of the Direction- Setting Issues (DSIs) was "Risk-Informed, Performance-Based Regulation" (DSI-12). The Commission expressed its view on the matters that were discussed in the DSI-12 issue paper in a Staff Requirements Memorandum (SRM) issued on April 15, 1997. The SRM stated the Commission's general view that: (1) to accomplish the principal mission of the Nuclear Regulatory Commission (NRC) in an efficient and cost-effective manner, it will, in the future, focus (in a regulatory sense) on those licensee activities that pose the greatest risk to the public; (2) this focus can be accomplished by building upon probabilistic risk assessment (PRA) concepts-where applicable-or other approaches that would allow a risk-graded approach for determining high- and low-risk activities; and (3) 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 Agency's traditional defense-in-depth philosophy.

More specifically, regarding the Office of Nuclear Material Safety and Safeguards (NMSS), the SRM states:

> 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.

The application of risk-analysis methods to nuclear materials uses is guided by the PRA Policy Statement and the PRA Implementation Plan; however, as the SRM notes, a framework for applying such methods to nuclear materials has not been developed. The framework for reactors that is referenced in the SRM was transmitted to the Commission in November 1995. Since that time, the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Regulatory Research (RES) have made substantial progress toward completing the six-step process that was envisioned for implementing the SECY-95-280 framework. In particular, the staff issued draft NUREG-1602, five draft Regulatory Guides, and related draft Standard Review Plans for public comment. A proposed final revision of the general guide was transmitted to the Commission by SECY-98-015 and approved by the SRM of May 21, 1998. Proposed final revisions of the guides on inservice testing, technical specifications, and graded quality assurance were transmitted to the Commission by SECY-98-067.

The purpose of this paper is: (1) to present the staff's plan to develop a framework that would guide increased use of risk-informed, performance-based (RIPB) approaches in NMSS regulation; and (2) to reexamine preliminarily the applicability of the RIPB approaches that are supported by Task 4 and 5 activities of the PRA Implementation Plan--primarily those for nuclear materials licensees and high-level waste (HLW) issues, but also those for low-level waste (LLW) disposal, spent fuel storage facilities, and transportation.

To establish an overall context, the paper starts with the definitions and discussion of regulatory approaches in the staff discussion of RIPB regulation (forwarded to the Commissioners' assistants by James Blaha on May 4, 1998. This is followed by a discussion of the need for a framework for the application of RIPB approaches to the regulation of nuclear materials uses and, for context, a description of the reactor framework that is referenced in the SRM of April 15, 1997. The paper then evaluates the applicability of the SECY-95-280 framework to nuclear materials regulation by considering four assumptions that are implicit, in this framework, in the context of nuclear materials uses, nuclear materials licensee communities, and the Agreement State program. Based on these considerations, the paper concludes that a framework for applying RIPB to nuclear materials uses is timely and that such a framework likely will differ from the reactor framework (e.g., in a framework for nuclear materials, PRA may be applicable to only a few specific uses and, for most licensed uses, other system analysis methods[5] that address the three risk questions will need to be considered instead). Finally, the paper discusses various issues that will need to be addressed before developing a nuclear materials framework. The staff's plan to address these issues and develop a nuclear materials framework is outlined in Attachment A. Attachment B, reexamines the applicability of the RIPB approaches that are now supported by the PRA Implementation Plan.

2. REGULATORY APPROACHES

It is useful first to establish a common understanding of RIPB and other regulatory approaches. The definitions and discussion in this section have been excerpted verbatim from the staff discussion of RIPB regulation.

Risk and Risk Assessment: The triplet definition of risk[6] is used in this paper because it defines risk at a fundamental level that can be applied to the entire range of activities involving NRC licensed use of Atomic Energy Act (AEA) materials. The risk triplet definition takes the view that when one asks, "What is the risk?" one is really asking three questions: "What can go wrong?" "How likely is it?" and "What are the consequences?"

The first question, "What can go wrong?" is usually answered in the form of a "scenario" (a combination of events and/or conditions that could occur) or a set of scenarios. Examples might include the failure of a valve to operate in a reactor or a syringe containing a radio-pharmaceutical being dropped in a hospital.

The second question, "How likely is it?" can be answered in terms of the available evidence and the processing of that evidence to quantify the probability and the uncertainties involved. In some situations, data may exist on the frequency of a particular type of occurrence or failure mode (e.g., accidental overexposures). In other situations, there may be little or no data (e.g., core damage in a reactor) and a predictive approach for analyzing probability and uncertainty will be required.

The third question, "What are the consequences?" can be answered for each scenario by assessing the probable range of outcomes (e.g., dose to the public) given the uncertainties. The outcomes or consequences are the "end states" of the analyses. The choice of consequence measures can be whatever seems appropriate for reasonable decision-making in a particular regulated activity and could involve combinations of end states.

A risk assessment is a systematic method for addressing the risk triplet as it relates to the performance of a particular system (which may include a human component) to understand likely outcomes, sensitivities, areas of importance, system interactions and areas of uncertainty. From this assessment the important scenarios can be identified.

Traditional and Probabilistic Approaches: All safety regulation ultimately is concerned with risk and addresses the three questions of the risk triplet. In practice, NRC addresses these three questions through the body of regulations, guidance, and license conditions that it uses to regulate the many activities under its jurisdiction. The current body of regulations, guidance and license conditions is based largely on a "deterministic" approach. As described in the PRA Policy Statement, the deterministic approach to regulation establishes requirements for engineering margin and for quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist and establishes a specific set of design basis events (i.e., what can go wrong?). The deterministic approach involves implied, but unquantified, elements of probability in the selection of the specific accidents to be analyzed as design basis events. It then requires that the design include safety systems capable of preventing and/or mitigating the consequences (i.e., what are the consequences?) of those design basis events in order to protect public health and safety. Thus, a deterministic approach explicitly addresses only two questions of the risk triplet.

A probabilistic approach to regulation (also described in the PRA Policy Statement) considers risk (i.e., all three questions) in a more coherent and complete manner. The probabilistic approach explicitly addresses a broad spectrum of initiating events and their event frequency. It then analyzes the consequences of those event scenarios and weights the consequences by the frequency, thus giving a measure of risk.

"Risk Insights" and "Risk-Informed" Approach: The term "risk insights," as used here, refers to the results and findings that come from risk assessments. The most fundamental results relate directly to public health effects, as in the Commission's Safety Goals. For specific applications the results and findings may take other forms. For example, for reactors these include such things as identification of dominant accident sequences, estimates of core damage frequency (CDF)[7] and large early release frequency (LERF)[8], and importance measures of structures, systems, and components. In other areas of NRC regulation, these include risk curves[9] for disposal facilities for radioactive wastes, frequency of accidental smelting of sealed sources at steel mills, frequency of occupational exposures, predicted dose from decommissioned sites and many others.

Risk insights have already been incorporated successfully into numerous regulatory activities, and have proven to be a valuable complement to traditional approaches. Given the current maturity of some risk assessment methodologies and the current body of event data, risk insights can be incorporated more explicitly into the regulatory process in a manner that will improve both the efficiency and effectiveness of current regulatory requirements.

A "risk-informed" approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. A "risk-informed" approach enhances the traditional approach by: (a) allowing explicit consideration of a broader set of potential challenges to safety, (b) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (c) facilitating consideration of a broader set of resources to defend against these challenges, (d) explicitly identifying and quantifying sources of uncertainty in the analysis, and (e) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions. Where appropriate, a risk-informed regulatory approach can also be used to reduce unnecessary conservatism in deterministic approaches, or can be used to identify areas with insufficient conservatism and provide the bases for additional requirements or regulatory actions.

"Performance-Based": A regulation can be either prescriptive or performance-based. A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. A performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including licensee, performance against clearly defined, objective criteria, (2) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (3) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. The measurable (or calculable) parameters may be included in the regulation itself or in formal license conditions, including reference to regulatory guidance adopted by the licensee. This regulatory approach is not new to the NRC. The Commission previously has approved performance-based approaches in 10 CFR Parts 20, 60, and 61. In particular, the Commission weighed the relative merits of prescriptive and performance-based regulatory approaches in issuing 10 CFR Part 60.

A performance-based approach can be implemented without the use of risk assessment. Such an approach would require that objective performance criteria be based on deterministic safety analysis and performance history. This approach would still provide flexibility to the licensee in determining how to meet the performance criteria. Establishing objective performance criteria for performance monitoring may not be feasible for some applications and, in such cases, a performance-based approach would not be feasible.

As applied to inspection, a performance-based approach tends to emphasize results (e.g., does the pump work?) over process and method (e.g., was the maintenance technician trained?). Note that a performance-based approach to inspection does not supplant or displace the need for compliance with NRC requirements, nor does it displace the need for enforcement action, as appropriate, when non-compliance occurs.[10]

As applied to licensee assessment, a performance-based approach focuses on a licensee's actual performance results (i.e., desired outcomes), rather than on products (i.e., outputs). In the broadest sense, a performance-based approach to regulatory oversight will focus more attention and NRC resources on those licensees whose performance is declining or less than satisfactory.

"Risk-Informed, Performance-Based": A risk-informed, performance-based approach to regulatory decision-making combines the "risk-informed" and "performance-based" elements discussed above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making. Stated succinctly, RIPB regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria based upon risk insights for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, and (4) focus on the results as the primary basis of regulatory decision-making.

3. FRAMEWORK FOR APPLYING PRA

NMSS has made several efforts toward using and developing risk-analysis methods to support existing or potential risk-informed regulatory approaches. Some of these efforts started as early as the mid-1970s. For example, the staff has been a developer of performance assessment (PA) methodology for geologic disposal of HLW and land disposal of LLW. NRC's effort has been both national and international in scope and its contributions include the development of Latin Hypercube Sampling, a method for propagating uncertainty that is commonly used in PRA and other risk-analysis methods, as well as in PA. NMSS' current efforts in PA were discussed with the Commission in a May 1997 briefing. Similarly, the staff made early efforts to apply PRA methods to gain a better understanding of transportation risks. Most notably, these included the "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170) and the "Transportation Modal Study" (NUREG/CR-4829). The Modal Study showed that the performance-based regulations for tests of spent fuel transportation casks provided adequate safety. In addition, the Modal Study has given the public a better understanding of the level of protection provided by spent fuel packages in transportation.

More recently, the staff has undertaken new efforts to use or develop risk-analysis methods for nuclear materials uses to satisfy a variety of purposes and objectives. For example, the staff sponsored a study that applied PRA methods to a new medical technology, Gamma Stereotactic Surgery. This study was the first step in gaining insight into the feasibility and advisability of applying PRA technology to medical devices. Similarly, a staff project is applying PRA technology to independent spent fuel storage installations (ISFSIs). Another recently started effort, the "Nuclear Byproduct Material Risk Review," is attempting to develop the basis for using a risk-graded approach to regulating the many uses of byproduct material that are under the jurisdiction of NMSS' Division of Industrial and Medical Nuclear Safety. Among other approaches, it will evaluate the possibility of using actuarial analyses of event data for this purpose. Finally, a recent paper, SECY-97-137, concerning proposed revision of 10 CFR Part 70, discusses the use of integrated safety analyses (ISAs) in the regulation of fuel cycle facilities.

The staff's approach has been appropriately flexible and developmental. However, as the number of staff efforts has grown and as resources become more scarce, there is an added need for technical and policy consistency and assurance that resources are being used judiciously. Accordingly, the development of a framework for applying PRA to nuclear material uses is timely. The staff expects to gain the same benefit from development of a nuclear materials framework as was gained by the development of the reactor framework.

4. THE FRAMEWORK FOR APPLYING PRA IN REACTOR REGULATION

In discussing the development of a framework for applying PRA to regulation of nuclear materials use, it is useful to summarize first the salient features of the referenced framework for use of PRA in reactor regulation (SECY-95-280). As described in SECY-95-280, the reactor framework is a general structure to ensure consistent and appropriate application of PRA methods. It has four parts. The first defines regulatory application areas in which PRA can play a role in NRC's decision-making process. The areas are grouped by the expected sophistication of the PRA required (ranging from PRAs based on generic data to state-of-the-art PRAs using plant-specific data). The second part entails an evaluation of the deterministic engineering considerations underlying the application area to ensure that the existing deterministic engineering approach is altered only after careful consideration. Factors to be considered include: defense-in-depth, the single-failure criterion, and appropriate codes and standards. The third part of the framework is an evaluation of risk issues in support of the proposed regulatory action. Elements of this evaluation include: scope and level of detail of the PRA, human and equipment reliability, sensitivity and uncertainty analyses, and assurance of technical quality. The final part integrates the deterministic and 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 risk and engineering conclusions of parts two and three.

As described in SECY-95-280, the framework is implemented through a six-step process. The first step is to identify specific regulatory applications that are amenable to expanded use of PRA information and to identify responsible staff organizations and pilot plants. The second is to conduct pilot programs for selected regulatory application areas. These projects provide insight into the treatment of issues, the selection of risk metrics, and the development of standards and guidance. The third step of the implementation process is to develop and document the acceptance process and criteria. The fourth step is to make near-term regulatory decisions in response to industry requests and initiatives. The fifth is to develop formal PRA standards, working with appropriate professional societies and industry groups. Finally, the sixth step is to make long-term modifications to the regulations, if necessary.

Development of the referenced framework served as a mechanism to figure out how to integrate a number of programmatic elements related to the application of PRA to power reactors. The framework provides a general structure to guide regulatory implementation of PRA. More specifically, it serves to ensure that: (1) fundamental regulatory principles are not overlooked in specific applications; (2) the development of processes and procedures for consistent implementation takes place; (3) pilot projects are used for testing of regulatory applications of PRA; and (4) there is an appropriate alignment of level of sophistication of analytic techniques (and their attendant costs and benefits) with risks (real and perceived).

In the time since the referenced framework was developed, the staff has made substantial progress toward completing the six-step implementation process. More specifically, the staff issued draft NUREG-1602, five draft Regulatory Guides, and related draft Standard Review Plans for public comment and has held a public workshop. A proposed final revision of the general guide was transmitted to the Commission by SECY-98-015 and approved by the SRM of May 21, 1998. Proposed final revisions of the guides on inservice testing, technical specifications, and graded quality assurance were transmitted to the Commission by SECY-98-067. Thus, the reactor framework now has advanced well beyond the description in SECY-95-280. The staff expects that it could develop a framework for applying risk-analysis methods to nuclear material uses that will be consistent with the purpose and principles of the framework for application of PRA in reactor regulation. To work out the specifics of a framework that would address the issues of greatest concern to NMSS, the staff believes that the more rudimentary framework of SECY-95-280 is the appropriate starting point and that the assumptions implicit in that framework must be considered carefully in the context of NMSS-regulated licensees and activities.

5. ASSUMPTIONS IMPLICIT IN THE REACTOR FRAMEWORK OF SECY-95-280 AND NMSS-REGULATED ACTIVITIES/LICENSEES

Although no attempt is made in this paper to note and discuss all the assumptions that are implicit in the SECY-95-280 framework for application of PRA in reactor regulation, as will be discussed in this section, four assumptions, in particular, do not generally apply to NMSS' regulatory situation. These are the following:

- PRA is the risk-analysis method of choice;
- A significant number of licensees desire broad and rapid implementation of RIPB regulation and have the technical and economic resources to support it;
- Integration of deterministic and probabilistic considerations is the pivotal issue in applying PRA in NRC's decision-making process; and
- Risk-analysis methods will be used by both staff and licensees.

To see why these assumptions that are clearly sound for the reactor program are not generally so for the nuclear materials program, it is necessary to first review the nature of the nuclear materials program.

In contrast with the reactor program, which regulates a few highly complex systems (i.e., types of reactors), the nuclear materials program regulates approximately 40 different activities, devices, and systems. In terms of complexity, these range from simple devices using low-activity sealed sources to large fuel-cycle facilities or a geologic repository for HLW disposal. The accident potential and hazard varies from one application to another and the initiators of concern vary too. The data that are available for risk-analysis include large sets of event data, which may be suitable for actuarial analyses of some uses (e.g., gauges); however, for others (e.g., a geologic repository for HLW), the data situation is more like that of reactors, so that a similarly predictive approach to risk-analysis is needed. Moreover, nuclear materials systems differ collectively from reactors in terms of engineering complexity, depth of safety systems, degree of reliance on human actions to assure safety, training and sophistication of personnel, and the degree to which administrative controls may be assumed to be reliable. In summary, the nuclear materials program involves about 40 activities, devices, and systems that differ significantly from one another and from reactors. These differences will be important considerations in applying RIPB approaches to specific nuclear materials uses.

Again, in contrast with the reactor program, which regulates a few tens of fairly similar licensees, there are estimated to be more than 20,000 NRC and Agreement State materials licenses held by not quite as many thousands of licensees. They are as varied as the regulated uses of nuclear materials. Although some materials licensees are large enough entities to be able to marshal significant technical and economic resources, most cannot. The smaller commercial firms, in particular, operate in highly competitive economic environments and have only the technical and economic resources that are essential for conducting their business. Thus, some materials licensees have fairly significant (nuclear) technical resources at their disposal, but most have very few. Some materials users have trade associations with a strong (nuclear) technical capability, but most do not. Moreover, in some cases where trade associations exist, the competitive nature of the business does not allow for significant sharing of technical information. Finally, nuclear materials licensees, in general, have fewer technical and economic resources, than reactor licensees, that can be brought to bear on radiation safety. In brief, the materials program involves roughly 20,000 licensees most of which differ significantly from one-another and from reactor licensees. These differences will be important considerations in applying RIPB approaches to specific nuclear materials uses.

Yet another potentially important consideration in developing a framework for nuclear material uses is the Agreement State program. The majority of materials licensees are regulated by Agreement States instead of NRC. This is quite unlike the reactor program in which all licensees are regulated directly by NRC. The Agreement States have a special relationship with the NRC in which NRC relinquishes its regulatory authority to such States which are then required to maintain adequate and compatible regulatory programs. The Agreement State regulatory programs vary greatly in terms of size and availability of technical and economic resources. In commenting on the DSI-12 issue paper, the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors noted that the paper failed to discuss the impact of compatibility determinations, by NRC, on RIPB regulations it promulgates. OAS expressed the concern that risk and cost/benefit analyses require assumptions to be made that may not be applicable to specific Agreement State circumstances, creating a significant conflict. In addition, although it was not explicitly raised in their comments, increased use of RIPB approaches could strain the resources of at least some Agreement States. Any effective framework must recognize the circumstances, abilities, and resources of the Agreement States.

In considering how well the four assumptions that were stated above represent the NMSS regulatory situation, it is useful to think in terms of NRC having jurisdiction over a number of "regulated systems." Each such system consists of: (1) a particular radioactive material (or group of materials); (2) an activity involving that material; (3) possibly a device or physical system that incorporates the material; and (4) the group of licensees that engage in the activity. When viewed from this perspective, the reactor program includes a few, quite similar regulated systems that are clearly well-represented by the four assumptions. It is less clear which, if any, of the roughly 40 nuclear materials regulated systems of concern to NRC and the Agreement States are also well-represented. In fact, preliminary consideration indicates that the representation is generally not good, but also suggests some promising directions for eventual development of a framework for nuclear material uses. The paragraphs below discuss each assumption in turn.

PRA is the risk-analysis method of choice: The staff believes that this assumption is not generally representative of nuclear materials regulated systems for two reasons. First, in its May 15, 1997, briefing of the Commission on the status of the PA program, the staff discussed how PA, like PRA, is a type of system analysis that addresses the three risk questions. Further, the staff discussed the types of systems to which PA applies and contrasted these systems with the type of systems to which PRA can be effectively applied. PRA and PA are only two examples of system analysis--there are, in fact, others that also can be used to address the three risk questions, but which are more or less appropriate for different systems and circumstances. The staff expects that a framework for applying risk-analysis technology to nuclear material uses will need to address the entirety of system analysis methods. This is not surprising and is consistent with how PRA came to be the method of choice for addressing the risk questions as they apply to reactors. Specifically, when the Atomic Energy Commission sponsored the first study intended to address realistically the risk questions for power reactors, the "Reactor Safety Study" (WASH-1400; NUREG 75/014), the investigators made a considered and deliberate choice when they adopted PRA. Subsequent to that initial choice, NRC and industry have gone to considerable effort to confirm, refine, and develop PRA specifically for power reactors. Similar considered and deliberate choices and likely some research and development will need to be made for the nuclear materials regulated systems. One consideration, but certainly not the only one, for making these choices, may be a graded approach to evaluation based on risk. For example, a straightforward dosimetric approach may show that the intrinsic risk posed by a device is only a small fraction of the dose limit for members of the public. Given such a situation, more sophisticated analyses may not be appropriate. (This approach is similar in concept to the screening approach used in the individual plant examination of external

events program.)

Second, and more fundamentally, PRA is a method of estimating risk for systems that have had too few end-point failures to permit an actuarial analysis. This is a principal reason for PRA having been chosen as the basis for the "Reactor Safety Study." The staff believes that for some materials regulated systems there are sufficient data to support actuarial analyses. Accordingly, the staff considers that risk analytic approaches other than PRA may enable it to better achieve the Commission's objectives--i.e., to expand the use of RIPB approaches and regulate commensurate with risk while using minimal additional resources.

A significant number of licensees desire broad and rapid implementation of RIPB regulation and have the technical and economic resources to support it: The staff believes that this assumption is not generally representative of nuclear materials regulated systems. To carry out the individual plant examination (IPE) program, reactor licensees made a significant investment in PRA. Having made this initial investment, most reactor licensees are positioned to support RIPB regulatory approaches and make effective use of their potential flexibility and possible cost reduction. In contrast, few materials licensees have done a PRA or have the resources to do one. This situation is reflected in the approximately 20 comment letters that addressed the nuclear materials use aspects of DSI-12. The letters came from Agreement States, large licensees, and organizations. Most of these commentors favored moving toward an RIPB approach in regulating radioactive materials, provided that it is done only if cost-effective. The commentors noted that, because of the diversity of activities regulated within NMSS, there would need to be differing approaches taken, depending on the nature of the circumstances. It also should be noted that, taken together, the commentors represent a fraction of materials licensees. The staff believes that the many small independent licensees that did not comment would be concerned about a potential drain of their limited resources resulting from RIPB approaches.

Integration of deterministic and probabilistic considerations is the pivotal issue in applying PRA in NRC's decision-making process: The staff believes that this assumption may not be generally representative of nuclear materials regulated systems. The governing regulations for some such regulated systems (e.g., Part 60, which is applicable to geologic repositories) embody a RIPB approach as they stand. In such cases, the integration of deterministic and probabilistic considerations is addressed in the existing regulations and guidance. Moreover, it is not clear from the outset that such integration generally would be the issue of greatest concern in applying RIPB approaches to other nuclear materials regulated systems. While that could be the case for some nuclear materials regulated systems (e.g. fuel cycle facilities), it may not be for others.

Risk-analysis methods will be used by both staff and licensees: The staff believes that this assumption may not be representative of nuclear materials regulated systems. Its validity will depend on the particular system analysis method and RIPB approach that might be chosen for a given regulated system. Accordingly, the staff views this as a consideration that would be addressed separately for each regulated system in developing the framework.

6. DEVELOPING A FRAMEWORK FOR APPLYING SYSTEM ANALYSIS TO REGULATION OF NUCLEAR MATERIALS

In the discussion of the previous section about certain assumptions that are implicit in the SECY-95-280 framework for reactors, several points were identified that would need to be addressed in developing a framework for applying system analysis methods to the regulation of nuclear materials. There also are several other points that would need to be addressed. These additional points are discussed below.

First, when the framework for applying PRA in reactor regulation was developed, a sound and extensive foundation of pertinent experience and policy already had been established. For the nuclear materials regulatory program, some elements of a foundation are in place, but there are important gaps that would need to be filled as part of the process of developing the framework. Although there are some regulated systems (e.g. the HLW repository area) for which the staff and licensees have had extensive experience with an appropriate system analysis method, this is not generally the case. For the most part the staff has started only in the last few years to investigate the applicability of PRA and other system analysis methods to nuclear material regulated systems. Not surprisingly, some applications appear promising and some less so. This is in marked contrast with the reactor situation prior to development of the framework. In that program, there had been WASH-1400, the IPE program, NUREG-1150, and pilot projects, in addition to a body of research that had been conducted by NRC, the Electric Power Research Institute and others both nationally and internationally. As a result, much was already known about what worked and what did not, when the framework was developed.

The staff now has several nuclear-materials-related projects underway that are part of the PRA Implementation Plan. These projects are discussed in Attachment B to this paper. In part, the intent of these projects is to test or develop system analysis methods for certain nuclear material regulated systems. The staff believes that such studies are an essential aspect of determining which nuclear materials regulated systems may be amenable to RIPB approaches. Therefore, as these projects continue, the staff intends to use the knowledge gained as input to its effort to develop a framework for applying system analysis methods to nuclear materials regulated systems.

Relative to the reactor situation, there also may be some important policy gaps. When the SECY-95-280 framework was developed, the Commission's policy statement on a safety goal for reactors had been issued. No similar policy statement exists for materials use. The DSI-12 commentors raised the issue of whether one is needed. There are some obvious advantages to having one. Specifically, such a statement could serve as the vehicle for promulgating the Commission's objectives in applying system analysis methods to nuclear materials uses. It could also serve to address issues that pertain to assuring that resource expenditures are commensurate with risk. These resource allocation issues could be very complex because system analysis methods used for different regulated systems are expected to vary. Also, public perceptions of risk must somehow be given appropriate account. However, the development of such a policy statement for nuclear materials uses could be challenging. Not only would it have to address the roughly 40 regulated systems that constitute nuclear materials use, but it would also have to address the fact that these systems currently have risk levels that vary and are set implicitly from several, at times conflicting, sources (i.e., EPA, the International Commission on Radiation Protection, the National Committee on Radiation Protection, the Uranium Mill Tailings Radiation Control Act of 1978, etc.). In addition, the issue that is now of some interest, in the reactor area, about whether a safety goal that was developed for a class of facilities should also apply to individual facilities also may be germane to the materials area. The staff's plan for developing a framework provides for a recommendation to the Commission on whether such a policy statement should be developed.

Another policy issue that the staff believes will need to be addressed before developing a framework arises from the following considerations: (1) the licensees associated with most nuclear materials regulated systems have evinced no groundswell of interest in a transition to RIPB approaches; and (2) the staff is not aware of any inadequacies in protection of public health and safety that would require substantial change in its current regulatory approaches with respect to these systems; however, the staff recognizes that the IPE program found potential vulnerabilities in a number of licensed reactors. Accordingly, the staff believes that criteria are needed to determine whether such regulated systems are, in fact, appropriate candidates for RIPB regulation. The staff's plan for developing a framework provides for recommending such criteria to the Commission.

Second, when the SECY-95-280 framework was developed, the fundamental viability of risk-informed regulation based on the use of PRA was not in question. The situation regarding many nuclear materials regulated systems is different. Consistent with the above discussion of assumptions, before it could develop a framework, NMSS would need to give careful consideration to the potential for applying some combination of a risk-informed approach and a system analysis method to each regulated system. Such consideration would have to include several factors related to each such system. More specifically, each choice would depend on such factors as hazard, device or system complexity, failure modes, analytic method complexity, licensee technical resources, licensee economic resources, staff resources, and likely others. Thus the staff's plan includes the selection of RIPB approaches and system analysis methods that are appropriate for different regulated systems and the criteria for making these choices. Because Agreement State and licensee input would be valuable, if not essential, in this process, the staff's plan includes workshops at appropriate points. Once potential associations have been identified, the need for pilot projects may be identified. The staff also recognizes, however, that any such projects will have to be conducted with limited resources. Accordingly, the staff's plan for developing a framework includes development of criteria to prioritize future pilot projects.

Third, in the staff's plan, development of the framework itself first would include careful consideration of current NRC regulatory approaches to identify any fundamental regulatory principles (e.g., defense-in-depth) that the framework should preserve. Once such principles were identified, in analogy with the SECY-95-280 framework, the "parts" of the framework and implementation steps would be developed. The staff would intend to use as much of the reactor framework as is practicable. Because of the special concerns of the Agreement States, the staff would work closely with them throughout development of the framework.

Finally, the staff would determine what staff training would be needed to implement the framework. In the past, nuclear materials risk-analysis training needs have been limited and have been addressed through the occasional development of specialized courses (e.g., courses in PA for radioactive waste repositories and ISA for fuel cycle facilities). Development of the framework would present an opportunity and a need to take a broader, more long-term view.

The staff will start with a scoping effort in which it will (1) complete a preliminary association of appropriate risk assessment methods with licensed uses of nuclear materials and (2) as appropriate for each regulated use and in coordination with the Agreement States, identify how these associated risk assessment methods can best be used in a risk-informed regulatory framework for materials. The staff believes that this effort is an essential first step toward developing a framework and determining the ultimate feasibility of completing a framework, given NRC's resource constraints.

Carrying out this plan will require knowledge of system analysis and nuclear materials regulated systems. It will also require a sustained effort in which the knowledge gained from completion of one task serves as important input to the next. The staff believes that this can be accomplished best by a working group drawn from all NMSS divisions. To be most effective the working group also would include NRR/RES and Agreement State representation. Accordingly, the first step in the staff's plan is to establish such a group.

A milestone schedule for the staff's plan is provided as Attachment A.

7. CONCLUSION

In recent years, the staff's efforts to apply PRA and other system analysis methods to the regulation of nuclear materials have expanded from a relatively few, focused activities to include additional pilot and trial activities. The staff has intended that its efforts be consistent with the Commission's view that: (1) to accomplish NRC's principal mission in an efficient and cost-effective manner, it will, in the future, focus (in a regulatory sense) on those licensee activities that pose the greatest risk to the public; (2) this focus can be accomplished by building on PRA concepts-where applicable-or other approaches that would allow a risk-graded approach for determining high- and low-risk activities; and (3) the use of PRA technology should be increased in all regulatory matters, consistent with the state-of-the-art and NRC's safety philosophy.

The staff recognizes, however, that any increase in the use of system analysis technology must occur within a framework that will ensure that: (1) fundamental regulatory principles are not overlooked in specific applications; (2) the development of processes and procedures for consistent implementation takes place; (3) pilot projects are used for testing of regulatory applications of PRA; and (4) there is an appropriate alignment of level of sophistication of analytic techniques (and their attendant costs and benefits) with risks (real and perceived). The staff also recognizes that any such increase must be accomplished with a commitment of only minimal additional resources. Accordingly, the staff believes that it is timely to undertake the development of a framework for the application of RIPB approaches to nuclear materials regulated systems. Notwithstanding the many significant differences among the approximately 40 nuclear materials regulated systems and the contrasts between those systems and the reactor regulated systems, the staff will pursue development of a framework that will be consistent with the purpose and principles of the framework for application of PRA in reactor regulation consistent with the level of budgeted resources. Attachment A outlines the staff's current plans in this regard.

ATTACHMENT A

PLAN AND SCHEDULE TO DEVELOP A FRAMEWORK FOR APPLYING
RISK ANALYSIS METHODS TO THE REGULATION OF NUCLEAR MATERIALS

Activity	Completion Date
A. Establish a team from all NMSS divisions to complete Tasks B through D below. (Include Agreement State representation as soon as that can be arranged, and NRR/RES representation.)	July 1998
B. Preliminarily associate appropriate risk assessment methods with nuclear materials uses and identify how associated risk assessment methods could be used in a risk-informed, performance-based (RIPB) framework for nuclear materials.	November 1998
1. Identify groupings of materials uses that may be amenable to similar risk analysis methods.	
2. Develop criteria to match candidate risk analysis methods with regulated systems.	
3. Develop criteria to match regulated systems with risk-informed approaches.	
4. Relate groupings of materials uses to candidate risk-informed approaches using the above criteria.	
C. Determine which information from the regulatory activities that are Identified in the PRA Implementation Plan can contribute. (See Attachment B for a discussion of these activities.)	November 1998
D. Determine the scope of a framework for applying RIPB approaches to the regulation of nuclear materials. Evaluate the resources needed to develop such a framework and make a recommendation to the Commission about its feasibility, given NRC's resource constraints.	December 1998

E.	Recommend to the Commission: (1) whether a safety goal policy should be developed for nuclear material uses; and (2) criteria for imposing regulatory approaches when not requested by licensees.	TBD
F.	Identify and prioritize regulated systems that may be amenable to RIPB approaches.	TBD

1. Hold workshops for Agreement State and licensee input.
2. Develop criteria to match regulated systems with performance-based approaches
3. Develop criteria to prioritize pilot projects.
4. Identify and prioritize pilot projects.
5. Do a final re-examination of current approaches by applying the criteria.
6. Do a final review of the regulations and processes for candidate areas by applying the criteria.
7. Hold workshops for Agreement State and licensee feedback.
8. Incorporate workshop results.
9. Report progress to the Commission.

G.	Develop framework.	TBD

1. Identify fundamental regulatory principles in cooperation with the Agreement States.
2. In analogy with the SECY-95-280 framework, identify "parts" of a framework for nuclear materials uses.
3. Develop implementation steps.
4. Hold workshops for Agreement State and licensee feedback.
5. Incorporate workshop results.
6. Transmit framework to the Commission

H.	Develop a plan for staff training.	TBD

ATTACHMENT B

PRELIMINARY RE-EXAMINATION OF CURRENT RISK-INFORMED,
PERFORMANCE-BASED AND RISK-INFORMED, LESS-PRESCRIPTIVE APPROACHES

The Staff Requirements Memorandum (SRM) of April 15,1997, requested that the staff reexamine the applicability of its risk-informed, performance-based (RIPB) and risk-informed, less prescriptive approaches with regard to nuclear material licensees and to high-level radioactive waste (HLW) issues, to ensure that the needs of those licensees and those areas receive adequate consideration. In this appendix, the staff provides a preliminary response to the Commission's request. Consistent with the staff's belief that building a base of experience in system analysis methods is essential to successful implementation of RIPB approaches in the nuclear materials area, the staff has broadened the Commission's request to include the approaches that are supported by Tasks 4 and 5 of the "PRA Implementation Plan." However, the staff considers that only a preliminary response is possible now because some conclusions and priorities may well change as it proceeds with its plan to develop a framework.

The staff is undertaking an extensive project to update and consolidate all existing Division 10 regulatory guides (general), policy and guidance directives, and standard review plans, concerning nuclear material uses. To the maximum extent possible, the existing licensing guidance documents will be consolidated into NUREGs, containing both application and review information in one document for use by the regulated community and Nuclear Regulatory Commission reviewers. Those existing documents not readily lending themselves to consolidation will be updated. In addition to making the guidance documents "user friendly," the planned degree of prescriptiveness of the guidance will be consistent with the degree of risk associated with the use of byproduct material being addressed. The RIPB concept will be applied to the extent possible. For example, industrial radiography guidance will be rather prescriptive compared with guidance associated with the use of gas chromatography. As another example, the staff recently issued draft NUREG-1556, Volume 1, which takes a graded, more performance-based approach to licensing portable gauges and reduces the information needed in support of an application. The staff believes that this effort will benefit licensees while providing the staff with an opportunity to gain experience in formulating RIPB approaches.

Over the past decade, the staff has attempted, through its contractors, to quantify the risks associated with unaccounted-for devices, with limited success. In May 1995, the staff initiated an in-house risk assessment that employs the methodology currently used for reactor PRAs. The assessment includes establishing the probabilities of devices being lost, causing exposure to members of the public, entering the metals manufacturing stream, being smelted, and other incidents. The scope of the assessment comprises only industrial devices containing cesium-137 or cobalt-60, because of the relatively higher risk of these devices to health, safety, property, and the environment, and because, when smelted, these types of devices are of particular concern. The risk assessment is to be completed in September 1998. Once complete, the staff will evaluate the methodology to determine whether it can be used to develop similar risk assessments for other types of devices.

Recently, the staff started the nuclear byproduct material risk review to: (1) identify and document a technical basis for a risk-informed approach to the regulation of nuclear byproduct material; and (2) develop plans for a graded approach to nuclear byproduct material regulation based on risk information. This effort is using qualitative and, to the extent possible and reasonable, quantitative tools, to identify and evaluate risks associated with nuclear byproduct material systems. Its ultimate objective is to establish a risk-graded approach to regulating the Division of Industrial and Medical

Nuclear Safety's regulated systems by developing and applying an analytical risk-ranking model. This effort responds in a direct way to the Commission's direction, regarding Direction Setting Issue (DSI)-7 and DSI-12, that the staff focus its resources in a way that is commensurate with risk. The staff believes that this project may yield relatively straightforward ways (e.g., using event data in an actuarial approach) of achieving this objective for some nuclear materials regulated systems.

The staff has had a significant performance assessment (PA) program to address HLW issues for almost two decades. It is currently performing analyses that will support its upcoming review of the U.S. Department of Energy's (DOE's) viability assessment PA and its eventual rulemaking to develop a site-specific HLW disposal regulation for Yucca Mountain consistent with the Energy Policy Act of 1992. The staff considers that its PA program is consistent with comments made by DOE on DSI-12.

The staff has prepared a draft of a branch technical position (BTP) on PA for low-level radioactive waste (LLW) disposal facilities and has issued it for comment. The staff will analyze the comments and issue a final position in FY 1999. The staff had planned to conduct a test case analysis to illustrate the application of the BTP, but has had to defer the effort in favor of higher priorities.

Although there is no requirement in the current 10 CFR Part 70 for fuel cycle facility licensees to perform an Integrated Safety Analysis (ISA), the staff has encouraged such licensees to make formal commitments in their licenses to perform an ISA to identify the hazards at their facility, analyze how those hazards could result in accidents, and identify those items relied on to prevent or mitigate the accidents. For some facilities, qualitative methods are cost-effective; for high-risk facilities, or for high-risk systems within otherwise low-risk facilities, qualitative methods could be supplemented by quantitative methods if necessary data are available. As was recently communicated to the Commission in SECY-97-137, the staff continues to think that ISAs are an essential and appropriate element of RIPB regulation of fuel cycle facilities.

The staff has sponsored PRAs of transportation of radioactive materials, the results of which show that 10 CFR Part 71 provides adequate protection of public health and safety. The current staff position is to base future changes to Part 71 on RIPB criteria. An example of this would be the addition of the Type C package that was recently added to the International Atomic Energy Agency regulations for air shipment of large quantities of radioactive material. The new requirement emphasizes RIPB criteria.

The staff started testing an approach to applying PRA techniques to dry-cask storage systems. The approach consisted of a pilot PRA study of one dry-storage system design at one site and entailed the following:

- An analysis to identify and characterize the cask(s) and fuel damage that would be required to occur to reach the accident dose limits in 10 CFR 72.106(b).
- A comprehensive analysis to identify potential sequences that could lead to the consequences identified above.
- For sequences identified, a probabilistic analysis to determine the likelihood of the sequences.

This study originally was scheduled for completion in FY98; however, it has now been suspended consistent with current budget constraints. Potentially, the results of this study could have been used to support the adequacy of the existing dry-storage system designs, procedures, and regulations. Also, the results were expected to be used to make recommendations about the extent to which an expansion of PRA methods for dry-cask storage would provide further useful information. The staff believes this study should be resumed when resources permit.

ATTACHMENT 2

PRELIMINARY REVIEW OF NUCLEAR MATERIALS REGULATIONS AND PROCESSES

The Staff Requirements Memorandum (SRM) of April 15, 1997, in part requested that the staff perform a review of the basis for nuclear materials regulations and processes, and identify and prioritize those areas that are either now, or could be made, amenable to risk-informed, performance based (RIPB) or risk-informed, less-prescriptive approaches, with minimal additional staff effort/resources. In this attachment, the staff surveys the nature of the nuclear materials regulations and processes. The staff believes that a final response to the Commission's request must await completion of several steps in its plan to develop a framework and will provide that response on completion of those steps.

The structure of the regulations and the associated licensing and inspection processes for materials reflect risk to varying degrees. For example, very low quantities of certain radionuclides may be distributed to individuals exempt from regulation. Devices that are typically low in risk are distributed through a general license approach with minimal Nuclear Regulatory Commission (NRC) oversight. Higher-risk devices (e.g., irradiators and industrial radiography devices) are subject to specific licensure and inspections. In general, the inspection (in both frequency and intensity) of nuclear materials licensees is based upon the type and quantity of byproduct material being used and therefore upon qualitative risk considerations.

The overarching 10 CFR Part 20 contains quantitative radiation protection standards that apply to all licensees. These standards establish limits on allowable doses (which can be converted to risk) and in Part 20 are implemented using a fundamentally performance-based approach. Thus, the central standards on which all nuclear materials regulation is ultimately based are implemented at a first level using a risk-informed, performance-based regulatory approach. At a second level, Part 20 contains prescriptive requirements that preclude some of the more likely events that could result in overexposure and prescriptive requirements of an administrative nature.

Parts 20 and 30 through 33 of the 10 CFR , in and of themselves, contain the essential requirements for licensing uses of byproduct material. Although they contain a number of prescriptive requirements (many of which are administrative), their fundamental approach is performance based. For some uses of byproduct material, radiography, medical uses, irradiators, and well-logging, there is both a potential for and had been a history of overexposures. In consequence, a third level of prescriptive requirements, those of Parts 34 through 39, were developed to reduce the frequency of overexposures related to those specific uses of byproduct materials.

10 CFR Parts 20 and 40 contain the essential requirements for licensing source and certain byproduct material, including the disposition of uranium mill tailings. At a first level, the approach is again performance-based. However, at a second level Part 40 imposes a number of prescriptive requirements. Some licensees have argued that aspects of NRC's implementation of the uranium mill tailings regulations (e.g., some license conditions) have been unnecessarily burdensome, overly prescriptive, and not warranted *vis a vis* costs and benefits. The office of Nuclear Material Safety and Safeguards (NMSS) has adopted a new licensing approach, for uranium recovery facilities, that provides licensees with more flexibility in the way they meet the conditions of their licenses, and allows licensees to make changes to their facilities or operations, under certain conditions, without involving the NRC.

10 CFR Parts 20 and 60 contain the essential requirements for licensing geologic repositories for high-level radioactive wastes (HLW). At a first level the regulatory approach is performance based. It is also risk-informed. However, at a second level, Part 60 contains many deterministic and prescriptive requirements. In developing site-specific HLW regulations for Yucca Mountain, the Commission has endorsed and the staff is adopting a more RIPB approach than is embodied in Part 60.

Like Part 60, 10 CFR Part 61 contains many deterministic and prescriptive requirements. Thus, Parts 20 and 61, which are the basis for licensing shallow land burial of low-level radioactive wastes (LLW), provide a fundamentally RIPB regulatory approach for LLW facilities supplemented at a second level by a more deterministic and prescriptive approach.

Operators of fuel cycle facilities are required to meet 10 CFR Part 20 requirements and are licensed to possess special nuclear material under 10 CFR Part 70. Part 70 primarily has requirements that are prescriptive, but it does include risk-informed elements (e.g. an emergency plan is required if credible releases of radioactive material result in doses to the public in excess of specified levels).

The regulations of 10 CFR Part 71 are mostly prescriptive and deterministic. However, the type B package test requirements for normal and accident conditions are performance-based. Complications arise in implementing RIPB changes to Part 71 because of the impact changes would have on the international community and other Federal regulatory bodies. More specifically, because transportation regulations affect international and interstate commerce, other entities are involved. The International Atomic Energy Agency (IAEA) develops model regulations through an international consensus process and the United States and other nations make reasonable efforts to be consistent with the IAEA regulations so that international trade is not burdened unnecessarily. Similarly, the U.S. Department of Transportation (DOT) has broad regulatory authority over transportation in the United States and NRC regulations must be consistent with those of DOT.

Independent spent fuel storage installations and monitored retrievable storage facilities must meet Part 20 and Part 72. The regulations under Part 72 are generally deterministic and prescriptive. The extent to which Part 72 could be changed to reflect a more RIPB format is limited by the directive of Section 218(a) of the Nuclear Waste Policy Act of 1982, which states: "...The Secretary [of DOE] shall establish a demonstration program in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission." A major shift toward risk-informed regulations pertaining to design criteria would require site-specific, probabilistic hazards analyses and, therefore, would require site-specific approvals by the Commission.

Safeguards requirements are found in 10 CFR Parts 73-75. Physical protection of plants and materials is addressed in Part 73. This part is predominantly deterministic and contains many prescriptive requirements. Power reactor licensees have expressed the opinion that Part 73 is too prescriptive. Part 74 contains the requirements for control and accounting of special nuclear material. It has performance-based and prescriptive elements. Part 75 is also deterministic and prescriptive in its approach.

10 CFR Part 76 contains requirements that are prescriptive, performance-based, risk-informed, and deterministic. For example, the requirements for material control and accounting are similar to the performance-based and prescriptive requirements of 10 CFR Part 74. Section 76.35 has a performance-based character in requiring descriptions of equipment and management controls that are necessary to protect health and safety. The criticality monitor requirements have a risk-informed component in that they must be capable of detecting prescribed dose levels. The requirement to assess accidents is an example of deterministic regulation.

The above summary illustrates the variety of regulatory approaches that are incorporated in NMSS' regulations and processes. There may well be potential to shift the balance more toward RIPB approaches; however, the staff believes that it is premature to make that determination.

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1. Kaplan, S. and B.J. Garrick, "On the Quantitative Definition of Risk," Risk Analysis, Vol. 1, No. 1, March, 1981.

2. CDF is the frequency of the combinations of initiating events, hardware failures, and human errors leading to core uncovery with reflooding of the core not imminent.

3. LERF is the frequency of those accidents leading to significant, unmitigated releases from containment in a time-frame prior to effective evacuation of the close-in population such that there is a potential for early health effects.

4. Risk curves are estimates of the probability that a given consequence will be exceeded.

5. There are many definitions of the term "system analysis." The "Fault Tree Handbook" (NUREG-0492) offers the following: "System analysis is a directed process for the orderly and timely acquisition and investigation of specific system information pertinent to a given decision." The fault tree method, a deductive method of system analysis, is the principal focus of NUREG-0492; however, the NUREG also discusses the event tree method and several other inductive methods of system analysis.

6. Kaplan, S. and B.J. Garrick, "On the Quantitative Definition of Risk," Risk Analysis, Vol. 1, No. 1, March, 1981.

7. CDF is the frequency of the combinations of initiating events, hardware failures, and human errors leading to core uncovery with reflooding of the core not imminent.

8. LERF is the frequency of those accidents leading to significant, unmitigated releases from containment in a time-frame prior to effective evacuation of the close-in population such that there is a potential for early health effects.

9. Risk curves are estimates of the probability that a given consequence will be exceeded.

10. Not every aspect of licensed activities can or should be inspected using this approach. For example, if a licensee is unsuccessful in meeting the criteria defined by a performance-based regulation, the inspector should then focus on the licensee's process and method, to understand the root cause of the breakdown in performance, and to understand how future poor performance may be avoided.