U.S. NUCLEAR REGULATORY COMMISSION PROCESS FOR RISK-INFORMING THE NUCLEAR WASTE ARENA

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ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) is increasing the use of risk insights and information in its regulation of nuclear materials and waste. The objective of this risk-informed regulatory effort is to improve the effectiveness and efficiency of the agency, while maintaining or increasing its focus on safety. The agency's Office of Nuclear Material Safety and Safeguards (NMSS) proposed a five-step process to carry out a framework for increasing the use of risk information and insights in its regulation of nuclear materials and waste. The office is carrying out the five-step process to risk-inform the nuclear materials and waste arenas. NMSS's actions included forming a Risk Task Group and the use of case studies to test and complete screening criteria for identifying candidate regulatory applications amenable for risk-informing. Other actions included involving stakeholders through enhanced public participation, developing safety goals for materials and waste regulatory applications, and establishing a risk training program for staff. Through the case studies, NRC staff found the draft screening criteria to be effective in deciding regulatory areas that may be amenable to an increased use of risk insights. NRC staff also found that risk information may have the potential to reduce regulatory burden and improve staff's efficiency in making decisions, while maintaining safety. Finally, staff found that it would be possible to develop safety goals for the nuclear materials and waste arenas.

INTRODUCTION

The agency's evolution in its adoption of the risk-informed and performance-based regulatory approach has guided NMSS's actions for developing the risk-informing process. Several steps in the agency's evolution have provided valuable guidance. Development of the policy on the use of probabilistic risk assessment methods was a critical step. NRC completed its policy statement (1) which influenced NRC's mid-1990s strategic rebaselining initiative. One issue addressed in the initiative was the idea of risk-informed, performance-based regulation. NRC also addressed this topic in a Commission-endorsed, staff white paper (2). Subsequently staff proposed to the Commission an approach for increasing the use of risk information (3) and proposed a framework to carry out the approach (4). Staff has been carrying out this framework for the materials and waste arenas since 1999. Part of the implementation process included the use of case studies (5). Staff selected the subject matter of the eight case studies to represent a broad spectrum of activities regulated within NMSS. They included studies on three types of devices that use radioactive material in the form of sealed sources: gas chromatographs, static eliminators, and fixed gauges. The other case studies represented specific regulatory actions on: site decommissioning; uranium recovery; radioactive material transport; the seismic evaluation of a gaseous diffusion plant; and spent fuel interim storage. Staff used these studies to identify gaps in the methods, data, and guidance necessary to risk-inform materials and waste regulation. NMSS is using the case study results (6) to develop draft safety goals for the materials and waste

arenas. The insights gained from these studies have also supported NMSS continued implementation of the framework to risk-inform its activities.

The objectives of this paper are threefold. First, the paper describes the Commission's actions that led to NRC adopting a risk-informed and performance-based regulatory approach. Second, the paper addresses how NMSS is carrying out a framework for increasing the use of risk information and insights in its regulation of nuclear materials and waste. As part of that discussion the paper also describes the NMSS risk-informing process which staff applies to both the waste and material arenas. Finally, the paper presents insights from waste-related case studies and discusses issues staff is addressing during development of the draft safety goals for NMSS.

DISCUSSION

Development of a Risk-Informed and Performance-Based Approach

The agency began to develop a policy statement on the use of probabilistic risk assessment methods in the mid-1990's. NRC completed its final policy statement on the "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" in 1995 (1). Also in 1995 staff presented to the Commission a framework for applying probabilistic risk assessment for regulating reactors (7). The Commission also conducted a Strategic Assessment and Rebaselining Initiative during the mid-1990's. In the NRC Strategic Assessment and Rebaselining initiative, one of the Direction-Setting Issues (DSIs) was "Risk-Informed, Performance-Based Regulation" (DSI-12). The Commission expressed the view that it will focus on those licensed activities that pose the greatest risk to the public to carry out the principal mission of the NRC in an efficient and cost-effective manner. Where applicable, this focus could be accomplished by building on probabilistic risk assessment (PRA) concepts or other approaches that would allow a risk-graded approach for determining high- and low risk activities. The Commission expressed its view on the matters in a Staff Requirements Memorandum (SRM) issued in 1997 (8). On 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 probabilistic risk assessment to nuclear material uses similar to the one developed for reactor regulation (SECY-95-280), where appropriate.*

In response to this Commission direction, staff informed the Commission, in SECY-98-138, of its approach for increasing the use of risk-informed, performance-based regulation in NMSS (3). Staff suggested that a framework for applying PRA to nuclear material uses was likely to differ from the framework for applying PRA to reactor regulation. This difference is because of important differences between nuclear material uses and reactors and between their respective

licensee communities. Staff subsequently proposed to the Commission a framework for increasing the use of risk information and insights in its regulation of nuclear materials and waste (4). The proposal included five-steps to carry out the framework. The proposed steps were:

> Step 1. Identify the specific regulatory applications that are amenable to expanded use of risk assessment information and identify responsible staff organizations.
>
> Step 2. Decide how to modify the current approach of the regulatory application areas that are determined to be amenable to risk-informed approaches.
>
> Step 3. Make the suitable changes to the rules and regulations, staff review plans, and Regulatory Guides.
>
> Step 4. Train staff to assure consistent and knowledgeable implementation of the new risk-informed approaches.
>
> Step 5. Develop or adapt needed tools.

The Commission directed staff (9) to move forward with its proposal and to develop appropriate material safety goals. The purpose of the material safety goals was to guide the NRC and to define what safety means for the materials program. The Commission directed (9) staff to use an enhanced participatory process and address avoidance of property damage in developing the safety goals. The Commission also directed staff to address critical groups as they related to different classes of material use and allow for equivalent levels of reasonable assurance of adequate protection across the spectrum of regulated materials activities. Finally the Commission directed staff to be consistent with risk-informed practices staff is applying to nuclear power plant regulation.

Implementation in the Waste and Material Arenas

NMSS's program on risk-informing materials and waste arenas has been described in detail elsewhere (10). Implementation of the five steps to risk-inform the nuclear materials and waste arenas included forming a Risk Task Group. Second, staff used case studies to test and complete screening criteria for identifying candidate regulatory applications amenable for risk-informing. The staff's implementation also includes involving stakeholders through an enhanced public participation process and establishment of a risk training program for staff. Finally staff is developing safety goals for materials and waste regulatory applications. NMSS's implementation of these activities is summarized below.

In response to Commission direction (9), NMSS realigned its resources and formally formed a Risk Task Group to carry out the Commission's directions. This group is composed of staff with diverse background and experience, with representatives from each NMSS division. Because of the crosscutting nature of the group's activities and findings the task group currently reports direct to the Director of NMSS.

To kickoff step one, staff developed draft screening criteria and held a public workshop in April 2000. Participants included representatives from NRC, other government agencies, professional societies, industry representatives, environmental and citizen groups, licensees, and private consultants. The workshop participant's consensus was the NRC's effort to increase the use of risk information in regulatory activities could be enhanced by studying cases in nuclear material and waste regulation. Staff conducted eight case studies, which were largely retrospective, using a standardized approach to evaluate the use of risk information in nuclear materials and waste regulation (5). The objectives of the case studies were fourfold. First, staff wanted to evaluate the effectiveness of draft screening considerations for identifying regulatory areas where risk-informed approaches would add value. Second, staff intended to evaluate the feasibility of developing nuclear materials and waste safety goals. Third, staff wanted to evaluate how risk information could improve NRC's regulation of nuclear materials and waste. Finally, staff wanted to identify the methods, data, and guidance needed to carry out a risk-informed regulatory approach. The case studies involved enhanced public participation. For instance, after the investigative phase of the studies, staff presented its preliminary conclusions at public meetings in which NRC invited all stakeholders to participate. Staff incorporated information and ideas that emerged from the meetings and produced individual reports documenting the case studies. A summary of, and insights resulting from, the case studies is available (6). Staff also consolidated and integrated the results from all the case studies into a final summary report (11). Through this integration effort, the staff formed insights into risk-informing regulatory actions that are more applicable to the spectrum of materials and waste regulatory program areas.

Following Commission direction, staff used an enhanced public participation process to carry out the framework for increasing the use of risk information and insights in its regulation of nuclear materials and waste. Stakeholder involvement was early (April 2000) and Risk Task Group staff used stakeholder comments to help create the case study approach. Participants at the April 2000 meeting also suggested that while performing the case studies, if feasible, NRC should develop safety goal parameters and a first draft of safety goals for each area. In September 2000 staff held another public meeting to get comments on the draft case study plan for carrying out the case studies. Also staff developed a communication plan for risk informing materials and waste regulations. During the individual case studies, staff conducted site visits to licensees, interviewed various stakeholders, and held many public meetings to seek feedback from its stakeholders. The staff also used these opportunities to communicate to the public NRC's findings and accomplishments, and explain the focus and reason of this work. After completing all eight case studies, NRC held an integration meeting to present the final screening criteria (Table I) and the early work on safety goal development.

NMSS has established a risk-training program for NMSS staff. This training program, developed in parallel with the case study effort, consists of three tiers (10). Staff have developed the tiers for different audiences (for example, Tier I is for NMSS managers and administrative staff) at different levels of intensity. For instance, a more-intensive Tier II course introduces NMSS technical staff to risk assessment concepts and methodologies applicable to NMSS, including a discussion of risk insights gained from several examples. Tier I and Tier II training equips staff with a basic familiarity of risk assessment to promote the use of a risk-informed approach in regulating nuclear material uses and waste disposal. Staff is developing Tier III courses for specialized training in risk assessment methods, risk communication, risk management, and risk

Table I. Screening Considerations for Identifying Regulatory Areas Where a Risk-Informed Approach Would Add Value

POTENTIAL BENEFITS OF A RISK-INFORMED REGULATORY APPROACH

(1) Could a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?

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

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

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

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

POTENTIAL FEASIBILITY OF IMPLEMENTING A RISK-INFORMED APPROACH

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

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

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

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

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

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

analyst qualification. Tier III training should lead to risk analysts who can perform risk assessments, draw risk insights, and create risk management strategies for the various areas that NMSS regulates. Staff updates the curriculum periodically to reflect advances in the NMSS risk-informing process and to make the latest applications, data and tools available to staff.

Developing safety goals for materials and waste regulatory applications is the final part of the NMSS program for implementation the Commission's guidance (9) for risk-informing the materials and waste arenas. Staff noted in SECY-99-100 (4) that, unlike the reactor arena, no safety-goal policy statement exists for materials and waste arenas. Safety goals for the materials and waste arenas will explain safety philosophy and help risk management by identifying the risk metrics that staff will evaluate. Material safety goals define what "safety" means for the materials program. A set of safety goals that assist the decision maker in deciding whether a regulatory action meets safety objectives is an important adjunct to risk information, when used for managing risks. The integrated results of the case studies showed developing safety goals for the nuclear materials, and waste arenas, is possible (6). Subsequently, staff has developed a first set of proposed first draft safety goals for the materials and waste arenas (11). NMSS is working with the Office of Nuclear Regulatory Research on development of draft safety goals. These efforts will continue to use enhanced public participation. Discussion of the draft safety goals and the issues staff are addressing is provided in a section below.

As result of all these activities, NMSS has developed a process which staff applies to both to the waste and material arenas (Fig. 1). Staff uses this process to discover whether a regulatory issue is amenable to a risk-informed approach, and if so, then staff can use the remaining steps to make a risk-informed decision. This decision process begins with identifying the regulatory issue or action alternative (for example, deciding on a petition for rulemaking). Staff apply the screening considerations (Table I), which address both the potential benefits and feasibility, to the issue to decide whether the issue is amenable to a risk-informed approach. Not all activities or regulatory issues addressed by NMSS may be subjected to a risk-informed approach. Specifically if it is not beneficial and feasible to apply a risk-informed regulatory approach, then staff will not use a risk-informed approach in the evaluation and decision process. The Risk Task Group is completing a staff guidance document on applying the screening considerations. In addition, the Risk Task Group is finishing a staff guidance document for performing a risk assessment that for NMSS activities. Staff is also developing another guidance document to address how staff can incorporate safety goals in the risk-informed regulatory decision process. Once completed, the three guidance documents will allow staff to apply consistently risk-information in regulatory decisions.

Case Studies Results

Staff conducted four waste-related case studies. The first study was Site Decommissioning of the Trojan Nuclear Power Plant. The second study was Transportation of the Trojan Reactor Vessel Package. The third study was Uranium Recovery. The final study was Seismic Exemption for Dry Cask Storage of Three Mile Island Unit 2 Fuel Debris at the U.S. Department of Energy's Idaho National Engineering and Environmental Laboratory (12). Staff has published the results of the case study on regulating spent fuel interim storage (dry cask) (13). The Risk Task Group also summarized the overall results of the eight materials and waste arena case studies (6). By using the case studies staff found the draft screening considerations to be effective in discovering regulatory areas in the waste arena that may be amenable to an increased use of risk insights. NRC staff determined that risk information in the waste arena may have the potential to reduce regulatory burden and improve the staff's effectiveness and efficiency in deciding, while

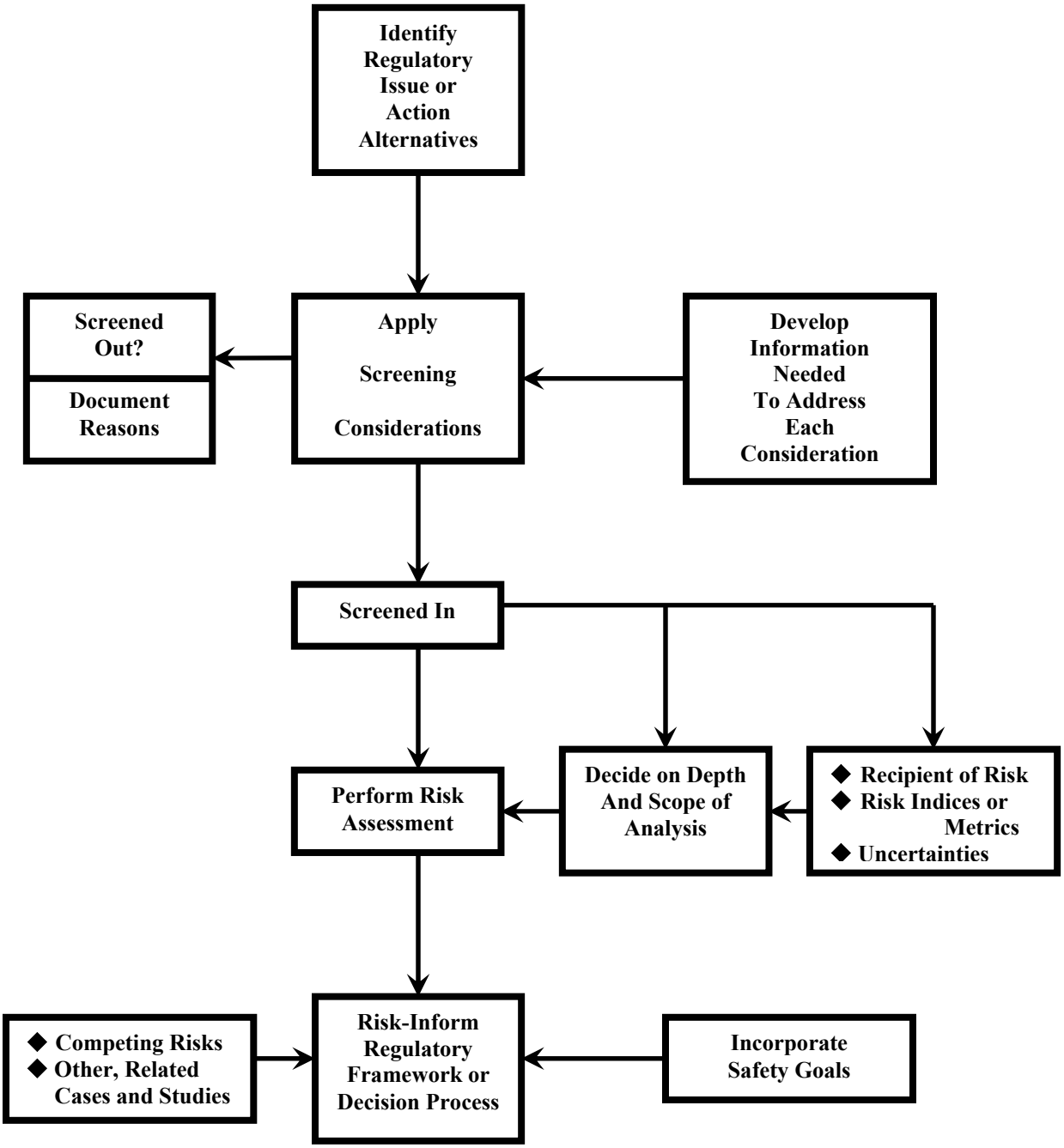

Fig. 1. NMSS Risk-Informed Decision Process

maintaining safety. The case studies proved that it would be feasible to develop safety goals for regulating nuclear materials and waste. The case studies have collectively shown that staff has used risk information for some time in deciding regulatory issues in the waste arena. The case studies were effective in showing where decisions or processes are consistent with the Agency's strategic goals. Also, they have helped to highlight some of the areas in which there are

drawbacks in the regulations or regulatory process. For instance, staff identified that they need to develop and carry out a robust and simple method for incorporating human factors and estimating human reliability. Staff found that human factors and human reliability applies to the wide range of situations and activities faced and performed by NMSS licensees. The case studies also highlighted that suitable guidance and training are key to realizing fully the benefits of a risk-informed approach. Developing guidance on the detail and complexity needed in the risk methods for various activities should be helpful to staff in plans for risk-informing materials and waste arenas. As noted above, staff is completing this guidance. The case studies provided insights for safety goals in the materials and waste arenas, and staff created preliminary safety goal ideas. Staff is developing further these safety goal concepts.

Issues Addressed in Developing Draft Safety Goals

Through the case studies and other related safety assessments staff determined that risks to the workers were significant in comparison to public risks. For some facilities, staff found chemical risks to be similar to or greater than the radiological risks. Thus, in developing materials and waste safety goals, and related metrics, NMSS would take these types of risks in consideration. Other issues staff is addressing in the NMSS safety goal development include those items required by Commission guidance (9). Staff is addressing avoidance of property damage and the critical groups as they related to different classes of material. Another area staff is addressing is the idea of allowing for equivalent levels of reasonable assurance of adequate protection across the spectrum of regulated materials. Consistency with risk-informed practices applied to nuclear power plant regulation is part of the safety goal development deliberations. Staff is addressing three other issues as part of developing safety goals. First, staff is discussing individual and societal goals. Second, staff is deliberating on worker and public risks. Finally, staff is assessing operational-phase risk and long-term risk, such as that associated with waste disposal sites or decommissioned sites. The Risk Task Group have documented these issues, tentative draft safety goals, which staff derived from the case studies and with input from the public, and a discussion of the three-tier safety goal structure (11). Staff is revising its communication plan to communicate more effectively to internal and external stakeholders the NMSS risk informing process and the role safety goals play in the process. NRC will continue to employ the enhanced public participation process in developing safety goals for the nuclear materials and waste arenas.

CONCLUSIONS

Since the Commission issued its policy statement in 1995 favoring the enhanced use of risk insights throughout the agency, the NRC has carried out actions to increase the use of risk information in regulatory decision-making. Direction from the Commission and valuable input from internal and external stakeholders gathered through enhanced public participation methods have guided NMSS's efforts to carry out a more risk-informed approach. NMSS has made progress in each of the five steps to carry out the approach that staff proposed to the Commission in 1999. Staff can use the screening consideration (Table I) and staff guidance to identify the specific regulatory applications that are amenable to expanded use of risk assessment information. The Risk Task Group has developed a training program to assure staff consistency and knowledge on carrying out the new risk-informed approaches and to provide more effective

risk communication. By using the case studies, and with involvement of each division within NMSS, current approaches of the regulatory application areas that staff has determined to be amenable to risk-informed approaches are being changed. Through these activities and future actions staff are and will make appropriate changes to the rules and regulations, staff review plans, Regulatory Guides, and inspection. Finally to address gaps identified in the case studies, such as a tool for a robust and simple method for incorporating human factors and estimating human reliability, the Risk Task Group is working with the Office of Nuclear Regulatory Research on development or adaptation of needed tools.

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