

**Plan for Using Risk Information in the
Materials and Waste Arenas**

CASE STUDIES

**Risk Task Group
Office of Nuclear Materials Safety and Safeguards**

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Plan for Using Risk Information in the Materials and Waste Arenas: Case Studies

1 BACKGROUND

In SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards (NMSS)," dated March 31, 1999, the Nuclear Regulatory Commission (NRC) staff proposed a framework for risk-informed regulation in the materials and waste arenas. On June 28, 1999, the Commission approved the staff's proposal. In the associated staff requirements memorandum, the Commission approved the staff's recommendation to implement a five-step process consisting of:

- (1) identifying candidate regulatory applications that are amenable to expanded use of risk assessment information;
- (2) making a decision on how to modify a regulation or regulated activity;
- (3) changing current regulatory approaches;
- (4) implementing risk-informed approaches; and
- (5) developing or adapting existing tools and techniques of risk analysis to the regulation of nuclear materials safety and safeguards.

Step one of the five-step process will be accomplished by applying screening criteria to regulatory application areas as a means to identify the candidate regulatory applications. To be a candidate for expanded use of risk information in the materials and waste arenas, regulatory application areas must meet the screening criteria.

As part of the staff's effort to use an enhanced public participatory process in developing the framework, the staff held a public workshop in Washington, DC, on April 25 and 26, 2000. The staff published draft screening criteria in a Federal Register Notice (65 FR 14323, March 16, 2000) announcing the workshop. The purpose of the first part of the workshop was to solicit public comment on the draft screening criteria and their applications. The purpose of the second part of the workshop was to solicit public input for the process of developing safety goals for nuclear materials and waste applications.

The workshop included participation by representatives from NRC, Environmental Protection Agency, Department of Energy, Occupational Safety and Health Administration, Organization of Agreement States, Health Physics Society, Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. A consensus among the workshop participants was that case studies and iterative investigations would be useful for the following purposes: (1) to test the screening criteria, (2) to show how the application of risk information has affected or could affect a particular area of the regulatory process, and (3) to develop safety goal parameters and a first draft of safety goals for each area.

2 PURPOSE

The purpose of the case studies is (1) to illustrate what has been done and what could be done in the materials and waste arenas to alter the regulatory approach in a risk-informed manner, and (2) to establish a framework for using a risk-informed approach in the materials and waste arenas by testing the draft screening criteria, and determining the feasibility of safety goals. Once the screening criteria have been tested using a spectrum of case studies, the criteria can be modified as appropriate, placed in final form, and established as part of the framework for prioritizing the use of risk information in materials and waste regulatory applications.

The case studies will be used to begin the process of developing safety goals for applications in the materials and waste arenas. Specifically, safety goal parameters (e.g., public, worker, acute fatality, latent fatality, injury, property damage, environment damage, safeguards, absolute vs. relative) should be identified in each study. Each case study will determine the feasibility of safety goals in that area. If feasible, a first draft of safety goals will be developed. The case studies will also be used to check for and test any existing risk-informed framework (e.g., defense-in-depth) in the material and waste arenas.

All case studies will have these general objectives. However, certain case studies may have specialized objectives. For example, as one type of test of the screening criteria, a case study will be chosen in an area that the staff intuitively feels might not pass the screening criteria. These additional objectives are discussed in the case study outline which is included in this plan.

The intent of the case studies is not to reopen or reassess previous decisions made by the staff and the Commission. The information gained by performing the case studies may impact future decisions to be made by the staff and the Commission.

Questions have been developed for each case study to answer. Answering these questions will guide the case studies to meet the objectives outlined below. Each case study will be of limited scope, but collectively, the case studies will cover a broad spectrum of regulatory applications in the materials and waste arenas. The case studies have been selected in areas that the staff believes would specifically help in establishing a framework, as well as areas that would help to set the groundwork for establishing safety goals.

3 OBJECTIVES

Case studies will have the following objectives:

- Objective 1: Produce a final version of screening criteria for the materials and waste arenas.
- Objective 2: Illustrate how the application of risk information has improved or could improve a particular area of the regulatory process in the materials and waste arenas.
- Objective 3: Determine the feasibility of safety goals in a particular area. If feasible, develop safety goal parameters, and a first draft of safety goals. If infeasible, document the reasons.

Objective 4: Identify methods, data, and guidance needed to implement a risk-informed regulatory approach.

4 DRAFT SCREENING CRITERIA

Draft screening criteria were published in Federal Register Notices announcing the April 2000 workshop and a September 2000 public meeting (65 FR 14323, 03/16/00, and 65 FR 54323, 09/07/00, respectively). On the basis of comments received at the workshop, the public meeting, and discussions with the NMSS Risk Steering Group, the criteria have been revised. The revised draft screening criteria are as follows:

- (1) Would a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?
- (2) Could a risk-informed regulatory approach improve the efficiency or the effectiveness of the NRC¹ regulatory process?
- (3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?
- (4) Would a risk-informed approach help to effectively communicate a regulatory decision or situation?

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

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

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

- (6) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC¹, applicant or licensee, and/or the public, and provide a net benefit? The net benefit will be considered to apply to the public, the applicant or licensee, and the NRC¹. The benefit to be considered can be improvement of public health and safety, improved protection of the environment, improved regulatory efficiency and effectiveness, improved communication to the public, and/or reduced regulatory burden (which translates to reduced cost to the public.)

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

¹For those regulatory processes in which Agreement States are involved, this criterion is applicable to Agreement States.

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

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

5 MEASURES OF SUCCESS

Success of the case studies will be measured by the following:

- (1) If, based on the testing of the draft screening criteria, final screening criteria are established, the case studies will collectively meet Objective 1.
- (2) If a case study can illustrate how the application of risk information has affected or could affect and improve a particular area of the regulatory process, the case study will meet Objective 2.
- (3) If a case study can determine the feasibility of establishing safety goals, and if feasible, develop the necessary safety goal parameters and a first draft of goals, the case study will meet Objective 3.
- (4) If a case study can develop the risk-informed regulatory approach sufficient to define the methods, data, and guidance needed and the feasibility of developing them, the case study will meet Objective 4.

When completed, the staff will present the results of the spectrum of case studies to the Commission.

6 CASE STUDY OUTLINE

- I. Revise draft screening criteria based on workshop and other suggestions (completed prior to September 21, 2000, meeting).
- II. Meet with the NRC historian and other appropriate individuals (NRC and non-NRC) for perspectives and insights on the materials and waste regulatory history.
- III. Review tables from the NRC-EPA risk harmonization effort and other sources such as the National Academy of Sciences study to uncover any implicit objectives (goals) under the existing regulatory framework. Glean insights on any potential underlying safety goals.
- IV. Case Study Areas:
 - A. Gas Chromatographs (*new and old designs, the line between general licenses and specific licenses for almost identical devices is unclear – illustrate how the*

application of risk information could improve a particular area of the regulatory process)

- B. Fixed Gauges *(some are specifically licensed, and others are under a general license; regulatory criteria for general versus specific license are not based on risk – illustrate how the application of risk information could improve a particular area of the regulatory process; also, this could be a test case for a safety goal on property damage)*
- C. Site Decommissioning - the study may focus on certain decommissioning incidents and certain selected sites *(elements of implied safety goals may be found in Commission decisions)*
- D. Uranium Recovery Facilities *(gaps in the regulations may be found; helpful in testing the screening criteria; if determined to be a good candidate for using risk, develop and use risk information for new Part 41 rulemaking effort)*
- E. Radioactive Material Transportation *(elements of existing, implicit safety goals may be found in Commission decisions; public confidence and communication issue)*
- F. Part 76 *(decide to use expanded risk information for gaseous diffusion plants or document the reasons why risk information will not improve the regulatory process in this area – contrast with new Part 70 approach; this decision-making process will be a good test for the draft screening criteria and will help establish consistency in applying risk information across materials and waste programs; also, possibly an area to look at chemical risks.)*
- G. Spent Fuel Interim Storage *(study probabilistic hazards analysis exemptions and proposed rulemaking – implicit safety goals may be found; public confidence issues and burden considerations)*
- H. Static Eliminators *(public confidence issue; risk communication issue – regulatory changes were made even though perceived risk was low)*

V Case study structure

- A. Develop a set of questions for all case studies to answer.
- B. Select a case-specific contact in each NMSS Division; obtain agreement with the Divisions on participation.
- C. Public meeting to announce our plan for case studies (September 21, 2000).
- D. Make any necessary revisions to plan based on input from public meeting.
- E. Develop detailed approach and timeline for each case study including the need and level of involvement of contractor support.

- F. Begin work on case studies.
 - G. Test screening criteria for each case study.
 - H. Answer all questions for each case study.
 - I. Meet with case-specific stakeholders as input to case studies.
 - J. Develop recommendations for safety goals (will be done in parallel with above).
 - K. Document results.
 - L. Conduct public meeting to present results of case studies.
 - M. Inform Commission of results.
- VI Assess the outcome and develop a plan to move forward.

7 DRAFT QUESTIONS FOR CASE STUDIES

7.1 Screening Criteria Analysis/risk Analysis Questions

- (1) What risk information is currently available in this area? (Have any specific risk studies been done?)
- (2) What is the quality of the study? (Is it of sufficient quality to support decision-making?)
- (3) What additional studies would be needed to support decision-making and at what cost?
- (4) How is/was risk information used and considered by the NRC and licensee in this area?
- (5) What is the societal benefit of this regulated activity?
- (6) What is the public perception/acceptance of risk in this area?
- (7) What was the outcome when this application was put through the draft screening criteria? Did this application pass any of the screening criteria? Does the outcome seem reasonable? Why or why not?

7.2 Safety Goal Analysis Questions

- (1) What is the basis for the current regulations in this area (e.g., legislative requirements, international compatibility, historical events, public confidence, undetermined, etc.)?

- (2) Are there any explicit safety goals or implicit safety goals embedded in the regulations, statements of consideration, or other documents (an example would be the acceptance of a regulatory exemption based in part on a risk analysis and the outcome)?
- (3) What was the basis for the development of the strategic goals, performance goals, measures and metrics? How are they relevant/applicable to the area being studied and how do they relate/compare with the regulatory requirements? How would they relate to safety goals in this area?
- (4) Are there any safety goals, limits, or other criteria implied by decisions or evaluations that have been made that are relevant to this area?
- (5) If safety goals were to be developed in this area, would tools/data be available for measurement?
- (6) Who are/were the populations at risk?
- (7) What are/were, and what could be/have been, the various consequences to the populations at risk?
- (8) What parameters should be considered for the safety goals (e.g., workers vs. public, individual vs. societal, accidents vs. normal operations, acute vs. latent fatality or serious injury, environmental and property damage)?
- (9) On the basis of the answers to the questions above, would it be feasible to develop safety goals in this regulatory area?
- (10) What methods, data results, safety goals, or regulatory requirements would be necessary to make it possible to risk-inform similar cases?

7.3 Questions upon Developing Draft Safety Goals

- (1) Are the current regulations sufficient in that they reflect the objectives of the draft goals? Would major changes be required?
- (2) Would the regulations need to be tightened?
- (3) Are the regulations overly conservative and/or too prescriptive with respect to the goals?
- (4) If these were the safety goals, what decisions would be made?
- (5) Would these goals be acceptable to the public?