

Part 2: Risk-Informed Regulation Implementation Activities

Chapter 2. Nuclear Materials Safety

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In the past, the Office of Nuclear Material Safety and Safeguards (NMSS) has used risk information in making regulatory decisions on a case-by-case basis. Because of the varied nature of the activities in the arenas within NMSS, a single approach, such as probabilistic risk assessment (PRA), is not possible.

Examples of NMSS's successful use of risk information in the past include: the relative risk analysis of the gamma knife; the analysis of the transport of the Trojan reactor vessel; the exemption issued for the TMI-2 fuel debris independent spent fuel storage installation (ISFSI); and the revisions to 10 CFR Parts 35 and 70. These activities were useful in developing experience in the use of multiple forms of risk assessment, as well as in learning the limitations of the methods when used in these arenas. NMSS has a number of activities underway to risk-inform its two arenas of interest -- Materials Safety and Waste Safety -- including the development of an overall framework for risk-informing these arenas to provide a more consistent approach to the use of risk information in our regulatory processes.

In SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the U.S. Nuclear Regulatory Commission (NRC) staff proposed a framework for risk-informed regulation in NMSS. In a Staff Requirements Memorandum (SRM), dated June 28, 1999, the Commission approved the staff's proposal, and directed the staff to develop appropriate materials safety goals, analogous to NRC's reactor safety goal, to guide the NRC and to define what safety means for the safety program. Quantitative safety goals developed for nuclear reactors have been used to express the Commission's expectations regarding "how safe is safe enough," and to provide a benchmark for comparing calculated risk measures.

As a first step toward developing a framework, the staff proposed establishing a systematic method to identify and prioritize the candidate regulatory applications that are amenable to expanded use of risk assessment information. This step 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 NMSS, 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, D.C., on April 25 and 26, 2000. The staff published draft screening criteria in the *Federal Register* (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 application. The purpose of the second part of the workshop was to solicit public input for the process of developing safety goals for nuclear material applications.

The workshop included participation by representatives from NRC, the U.S. Environmental Protection Agency, the U.S. Department of Energy, the U.S. Occupational Safety and Health

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

The NMSS staff decided to pursue case studies with the following purposes: (1) to illustrate what has been done and what could be done in NMSS to alter the regulatory approach in a risk-informed manner; and (2) to establish a framework for using a risk-informed approach in NMSS 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 NMSS regulatory applications.

In addition to the overall framework, NMSS is also actively using risk assessment techniques in a number of other specific areas, such as performance assessment in the high-level waste program, the integrated safety assessment for fuel cycle facilities, and hazard barrier analysis in the use of byproduct material. The specific implementation of these activities is further discussed in the following summaries.

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-1: Develop a framework for incorporating risk information in the NMSS regulatory process.*

In SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the NRC staff proposed a framework for risk-informed regulation in NMSS. In an SRM dated June 28, 1999, the Commission approved the staff's proposal. As a first step toward developing a framework, the staff proposed establishing a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information.

Based on stakeholder input, the NMSS staff decided to pursue case studies with the following purposes: 1) to illustrate what has been done and what could be done in NMSS to alter the regulatory approach in a risk-informed manner; and 2) to establish a framework for using a risk-informed approach in NMSS 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 NMSS regulatory applications.

The case studies will be used to begin the process of developing safety goals for NMSS applications. 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, and if feasible, a first draft of safety goals will be developed.

Each case study will be of limited scope, but collectively, the case studies will cover a broad spectrum of NMSS regulatory applications. A case study plan has been developed by the NMSS staff and the NMSS Risk Steering Group. The case studies have been selected in areas we believe would specifically help us to establish a framework, as well as areas that would help to set the groundwork for establishing safety goals. The staff and its contractor will begin working on case studies in October 2000. The staff anticipates working on several case studies simultaneously. When completed, the staff will present the results of the spectrum of case studies to the Commission.

* This implementation activity is also associated with the Nuclear Waste Arena

Additionally, the staff is working with the Office of Human Resources (Technical Training Center) to develop a class to train NMSS staff on risk activities in the materials and waste arenas. The pilot presentation of this class was held September 11-14, 2000. Feedback from the pilot class will be used to create a final version of the class, which will be implemented in December of 2000.

Milestones:

Public meeting to discuss case studies	September 21, 2000 (C)
Deadline for public comments on proposed case studies	October 5, 2000 (C)
Final case study plan	October 2000
Prioritize and schedule case studies; issue first statement of work	November 2000
Final version of NMSS risk training class developed; implement first class	December 2000

Assignment:

NMSS/RTG

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-2: Continue to develop improved risk assessment methods and data for calculating risk in support of risk-informed regulatory decision making.

Work is ongoing to systematically perform a risk analysis of byproduct materials to incorporate risk insights into NMSS regulatory activities, as discussed in SECY-99-100. In SECY-00-0048, "Nuclear Byproduct Material Risk Review," the staff transmitted, to the Commission, NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," and the staff's approach for use of the technical information. The staff's review of the analysis did not find any areas of regulation or policy needing immediate revision, to address a safety issue. The staff, with contractor support, is conducting an uncertainty analysis of some of the data. However, the staff has used, and will continue to use, the insights gained through the analysis, and will incorporate additional information as it becomes available. In addition to incorporating insights into NMSS risk efforts, the staff plans to use results documented in NUREG/CR-6642 to support the performance goals of the "Planning, Budgeting, and Performance Management" process, and to use the report and its supporting database as resources for evaluating risk issues in byproduct material activities:

- a) The staff is currently planning to use the risk information in NUREG/CR-6642 in its analysis of the "Petition for Rulemaking," PRM-36-1, which requests modification of 10 CFR 36.65(a) and (b). These regulations describe how an irradiator must be attended, to allow for the operation of a panoramic irradiator with qualified operators on site. The staff, with the assistance of a contractor, is conducting an assessment of the Petition with the basis of the models and information found in NUREG/CR-6642, in conjunction with information on historical irradiator accidents worldwide that may have been attributed to the lack of the presence of an onsite operator.
- b) The staff plans to use the risk information in NUREG/CR-6642, along with a proposed uncertainty analysis under development, in its review of the "Mallinckrodt Lessons Learned," and the possible subsequent revision of the Inspection Guidance. NMSS has established two working groups (Phase I and Phase II) to review the materials licensing and inspection program and provide recommendations. Phase I will review findings of the recent Mallinckrodt inspections in Region I and Region III that involved overexposures and to develop lessons learned for licensing and inspection, regulatory changes, and NRC/State jurisdiction. The lessons learned will be categorized as: 1) actions requiring short/long term changes to NRC programs and guidance; 2) actions requiring other regulatory changes (i.e. rulemaking); 3) actions to be considered in Phase II for review of the overall materials program; 4) issues requiring further

interactions with other agencies/jurisdictions; and 5) issues to be referred to and considered by the working group on event evaluation. Phase II will review the overall materials program and recommend necessary changes. The scope of the charter will be broad enough to capture events described in our performance measures. The recommendations may include regulatory changes, revisions to the existing licensing and inspection program, and changes to the enforcement policy. The working group will use as a guiding principle the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

Milestones:

- a) Visit irradiator sites October 5, 2000 (C)
- Draft risk analysis October 20, 2000
- Final risk analysis October 29, 2000

- b) Phase I working group formed August 2000 (C)
- Final Phase I group report December 2000
- Phase II working group initiated January 2001
- Final Phase II group report June 2001

Assignment:

NMSS/IMNS and NMSS/RTG

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-3: Incorporate risk information into the regulatory framework by revising 10 CFR Part 35, "Medical Use of Byproduct Material."

The Commission has approved the staff's proposal contained in SECY-99-201, which included the proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material." The revised rule focuses NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and establishes a risk-informed and more performance-based regulatory structure consistent with NRC's Strategic Plan. The staff used a risk-informed approach to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health. Risk information that was considered during the development of the rule included events in NRC's Nuclear Materials Event Database; the external review and report by the National Academy of Sciences-Institute of Medicine; a 1993 NRC internal management review and report; the Commission's Strategic Assessment and Rebaselining Project; and comments provided by the stakeholders and the public.

The staff is developing the final rulemaking package for the revision of Part 35, in accordance with the SRM on SECY-99-201, dated February 16, 2000. The Commission approved the rule language and directed the staff to complete the final Part 35 rulemaking package, the associated guidance document, and the revised "Medical Policy Statement." The final "Medical Policy Statement" was published on August 3, 2000 (65 FR 47654). The SRM noted that the rule is risk-informed and significantly reduces the regulatory burden in many areas.

Milestones:

Final rule published Contingent on Commission SRM
Final NUREG 1556-Vol 9 published Coincide with final rule publication

Assignment:

NMSS/IMNS/RGB

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-4: Incorporate risk information into the regulatory framework by amending Part 70 governing the domestic licensing of special nuclear materials in response to a “Petition for Rulemaking.”

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

In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach that had as its primary components: (1) the identification of consequence and likelihood performance requirements for prevention of accidents or mitigation of their consequences; (2) the performance of an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety; and (3) the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed.

Milestones:

Publish final rule	September 18, 2000 (C)
Publish ISA plan guidance	January 18, 2001
Publish backfit guidance	September 18, 2001
Resolve SRP issues and publish	December 31, 2001
Monitor licensee implementation	Ongoing

Assignment:

NMSS/FCSS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-5: Incorporate risk information into the regulatory framework by integrating insights contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Option for Nuclear Byproduct Material Systems."

The Division of Industrial and Medical Nuclear Safety continued its progress on guidance consolidation, including the integration of risk information, with the final publication of the following NUREG-1556, "Consolidated Guidance about Materials Licensees," volumes:

Vol. 6	"Program-Specific Guidance about 10 CFR Part 36 Irradiators"
Vol. 7	"Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope"
Vol. 11	"Program-Specific Guidance about Licenses of Broad Scope"
Vol. 13	"Program-Specific Guidance about Commercial Radiopharmacy Licenses"
Vol. 14	"Program-Specific Guidance about Well-Logging, Tracer, and Field Flood Study Licenses"

Future revisions will use the insights and information contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems."

Milestones:

First-round revisions published:

Vol. 6	October 2001
Vol. 7	December 2002
Vol. 11	April 2002
Vol. 13	September 2002

Assignment:

NMSS/IMNS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Performance Goal: Increase public confidence in NRC regulatory oversight.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-6: Work with stakeholders to revise the fuel cycle facility oversight program to increase the use of risk insights for monitoring and for responding to changes in regulated performance commensurate with the impact on risks.

In 1999, the staff initiated a revision of the fuel cycle facility safety inspection program as part of the re-inventing government process and consideration of lessons learned from several NRC initiatives for improving regulatory oversight, consistent with SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards (NMSS)." The staff's initiative was described in SECY-99-188, "Evaluation and Proposed Revision of the Nuclear Fuel Cycle Facility Safety Inspection Program." A task group comprised of Headquarters and Region staffs is working with stakeholders to develop the revised inspection program. In response to stakeholder comments, the staff broadened the initiative to encompass the entire oversight program for safety and safeguards. The revised oversight program will ensure safety and safeguards are maintained while optimizing regulatory burden. The program will include risk-informed inspections, risk-significance determination, more objective and predictable enforcement and assessment of licensee performance, and enhanced communications with stakeholders. The revised oversight program will build upon the risk-informed regulations associated with the new Part 70 rulemaking, and will focus on the results of licensees' ISAs.

Since beginning the initiative in May 1999, there has been an extensive outreach effort to involve stakeholders in the oversight program revision. Staff conducted seven public workshops with stakeholders to develop the framework and foundation for the revised oversight program, including cornerstones of safety and common defense and security. In this regard, stakeholders and staff have agreed on a foundation and framework for making the fuel cycle oversight program more risk-informed and performance-based. In the most recent public meeting with stakeholders held in September 2000, stakeholders and staff identified the priority and sequence for completing work necessary for the oversight program revision. The staff plans to inform the Commission on the status of the oversight program revision in a paper and briefing in December 2000.

Milestones:

Commission paper on status of oversight program revision November 28, 2000
Commission briefing on status of oversight program revision December 20, 2000

Assignment:

NMSS/FCSS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

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

Strategy 3: *We will confirm that licensees understand and carry out their primary responsibility for conducting activities consistent with the regulatory framework.*

Implementation Activity MS 3-1: Incorporate risk information into the regulatory framework by instituting a risk-informed, performance-based Temporary Instruction for the nuclear medicine program.

SECY-00-0001 and the associated SRM were issued on the staff's proposed medical pilot program (nuclear medicine program) to streamline inspection and enforcement of materials licensees. The approach assesses a licensee's performance relative to desired outcomes. A risk-informed, performance-based Temporary Instruction (TI) for the medical pilot program uses a focus element approach to assess a licensee's performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections.

Milestones:

TI Issuance April 24, 2000
End of pilot program One year after issuance date

Assignment:

NMSS/IMNS/RGB

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

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.*

Implementation Activity EER 1-1: Develop realistic assessments of risk impacts from radiation exposure.

Risk estimates are derived primarily from health effects at high doses. Regulations are based on a linear hypothesis of radiation protection. This hypothesis assumes that there is a direct relationship between dose and somatic damage and that there is no threshold below which no injury will occur. The regulatory consequence of this assumption is that the Agency's requirements for acceptable radiation exposure limits may be unnecessarily conservative.

Research is examining data on adverse health effects caused by long-term exposure to low levels of radiation and evaluating the realism of current health effects models. Research is also assessing individual and collective doses from materials contaminated with low levels of radioactivity, to support regulatory decisions on the release of such materials from regulatory control.

Milestones:

Complete final report on dose assessment for products and materials
exempt from licensing December 2000

Complete final report on individual doses to support
development of the clearance rule January 2001

Complete report on collective doses to support development
of clearance rule TBD

Provide technical input to guidance on sewer treatment facilities June 2001

Draft report of JCCRER studies to examine deterministic effects of
occupational exposure to radiation July 2001

Assignment:

RES