

June 2, 1999

SECY-99-147

FOR: The Commissioners

FROM: William D. Travers /s/  
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

PURPOSE:

To obtain Commission approval to publish a proposed rule amending 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

BACKGROUND:

A near-criticality incident at a low enriched fuel fabrication facility in May 1991 prompted the Nuclear Regulatory Commission (NRC) to evaluate its safety regulations for licensees that possess and process large quantities of special nuclear material (SNM). As a result of this review, the Commission [Staff Requirements Memorandum (SRM) dated January 15, 1993] and the staff recognized the need for revision of its regulatory base for these licensees and, specifically, for those possessing a critical mass of SNM. Further, the staff concluded that to increase confidence in the margin of safety at a facility possessing this type and amount of material, a licensee should perform an integrated safety analysis (ISA). An ISA is a systematic analysis that identifies: 1) plant and external hazards and their potential for initiating accident sequences; 2) the potential accident sequences and their likelihood and consequences; and 3) the structures, systems, equipment, components, and activities of personnel relied on for safety to prevent or mitigate potential accidents at a facility.

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The Nuclear Energy Institute (NEI) explained to the Commission industry's position on the need for revision of NRC regulations in Part 70 at a meeting on July 2, 1996, and in a subsequent filing, in September 1996, of a Petition for Rulemaking (PRM 70-7). In SECY-97-137, dated June 30, 1997, the staff proposed a resolution to the NEI PRM and recommended that the Commission direct the staff to proceed with rulemaking. The Commission, in an SRM dated August 22, 1997, approved the staff's proposal to revise Part 70 and directed the staff to submit a draft proposed rule by July 31, 1998.

The staff forwarded a draft proposed rule to the Commission in SECY-98-185, "Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated July 30, 1998. SECY-98-185 also discusses the history of this rulemaking. The staff briefed the Commission about the draft proposed rule at a Commission meeting held on August 25, 1998. NEI expressed its concerns with the proposed rule at the same meeting. After the Commission meeting, the rule was discussed at a public meeting that was held on September 29, 1998.

The Commission issued an SRM dated December 1, 1998, that directed the staff not to publish the proposed rule contained in SECY-98-185 for public comment. Instead, the Commission directed the staff to obtain stakeholder input and revise the draft proposed rule. In that SRM, the Commission also directed the staff to: (1) decide what is fundamental for NRC's regulatory purposes for inclusion as part of the license or docket and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures, for submittal, those few significant changes that currently would require license amendments; (2) require licensees/applicants to address baseline design criteria and develop preliminary ISAs for new processes and new facilities; (3) justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA; (4) require that any new backfit pass a cost-benefit test, without the "substantial" increase-in-safety test; (5) require the reporting of certain significant events because of their potential to impact worker or public health and safety; (6) clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration and other Government agencies; (7) critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and (8) request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

#### DISCUSSION:

As directed in the SRM for SECY-98-185, stakeholder input was solicited and obtained at public meetings held in December 1998, and January and March 1999. A website was established to facilitate communication with stakeholders and to further solicit input. The nuclear industry submitted comments by letters and postings on the website. The draft proposed rule in the Federal Register Notice (Attachment 1) takes into consideration all public comments received through April 16, 1999. Attachment 2 discusses how the staff addressed the issues contained in the SRM, namely: (1) whether the ISA should be in the license; (2) the change process; (3) baseline design criteria; (4) preliminary ISA; (5) decommissioning; (6) backfit; (7) reporting of events; (8) chemical hazards; (9) SRP modifications; and (10) ISA methodologies used in the licensing of new technologies. Attachment 3 discusses how the staff addressed the public comments.

The staff's proposed revisions to Part 70 are intended to provide a risk-informed, performance-based approach for increasing confidence in the margin of safety for licensees authorized to possess a critical mass of SNM, and address many of the weaknesses identified in NUREG-1324. The draft proposed rule: (1) requires that each licensee or applicant establish a safety program; (2) identifies performance requirements, consisting of consequences and associated likelihoods, that limit the risk of accidents at the facility; and (3) contains a change process that allows licensees to make certain changes to the safety programs or the facilities without NRC preapproval, only post-notification, and describes those changes that require NRC preapproval. The safety program consists of process safety information; an ISA that analyzes facility hazards and potential accident sequences, and identifies items relied on for safety; and management measures to ensure that items relied on for safety are available and reliable to perform their function when needed. The draft proposed rule requires that an ISA summary be submitted with the application and be included on the docket but not in the license. Facility changes, including changes reflected in the ISA summary, are discussed in 10 CFR 70.72 of the rule. The change process in that section of the rule reflects the staff's recommended approach, which is also strongly supported by the industry. The staff recommends this approach because it focuses on high-risk changes, contains straightforward, objective criteria, and is consistent with the direction in the SRM. This approach differs significantly from the 10 CFR 50.59 approach which was designed for reactors and considered by the staff. The §50.59-like approach that was considered by the staff is included as Attachment 4, for the Commission's consideration.

With one exception, the staff's approach is in accordance with the Commission's SRM of December 1, 1998. The exception is that a preliminary ISA (or preliminary hazard analysis) is not required. The industry opposed submitting such an analysis, and, after consideration of industry's view, the staff decided that its pre-licensing needs could be addressed through existing requirements in 10 CFR 70.21(f).

As in SECY 98-185, the staff continues to believe that a qualitative backfit mechanism should be considered for implementation only after the safety basis is established and incorporated in the license, and after licensees and staff have gained experience with the implementation of the ISA requirements of the rule. However, given the views expressed by industry, the Federal Register Notice requests public comment on the intent to defer implementation of a backfit provision in Part 70. A more detailed discussion of backfit is contained in Attachment 2.

The Federal Register Notice also specifically requests public comment on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities and on the NRC-OSHA interface with respect to regulation of chemical hazards.

Two draft guidance documents support the rulemaking, an SRP (Attachment 5), and an ISA guidance document (Attachment 6). The draft SRP provided as Attachment 5 to this Commission Paper reflects the results of extensive stakeholder interaction as it pertains to the SRP, including some of the more recent comments received. The staff continues to analyze the recent comments and will make further revisions to the SRP text, as considered appropriate. When the proposed rule is

published for comment, staff proposes to make available at that time the latest version of the draft SRP, i.e., reflecting additional revisions in response to the recent comments received.

The rulemaking package does not contain an enforcement and inspection plan. NMSS staff is developing a revised inspection program for fuel cycle facilities. As part of this activity, NMSS staff will address the inspection activities under the proposed rule, and will develop, with the

Office of Enforcement, an enforcement approach. As part of the final rulemaking, these issues will be addressed.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it. However, the rule amends information collection requirements that must be submitted to and approved by the Office of Management and Budget no later than the date the rule is published in the Federal Register.

RESOURCES:

Resources to complete and implement the rule are included in the current budget.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of proposed rulemaking for publication (Attachment 1).
2. Certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b)3.

Note:

1. The proposed rule will be published in the Federal Register for a 75-day public comment period;
2. A draft SRP will be available in the Public Document Room (Attachment 5);
3. A draft ISA Guidance Document will be available in the Public Document Room (Attachment 6);
- d) A draft "Regulatory Analysis" will be available in the Public Document Room (Attachment 7);
- e) The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it, as required by the Regulatory Flexibility Act;
- f) Copies of the Federal Register Notice of proposed rulemaking will be distributed to all affected licensees. The notice will be sent to other interested parties on request;
7. A press release will be issued (Attachment 8);

8. The appropriate Congressional committees will be informed (Attachment 9);
  - i) A draft Environmental Assessment will be available in the Public Document Room (Attachment 10);
  - j) An Office of Management and Budget (OMB) clearance package must be submitted to OMB no later than the date the proposed rule is submitted to the Federal Register.

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Attachments:

1. Federal Register Notice - Proposed Rule
2. Disposition of SRM Issues
3. Disposition of Public Comments
4. Section 70.72 Change Process Option 2
5. Standard Review Plan (Draft)
6. ISA Guidance Document (Draft)
7. Regulatory Analysis (Draft)
8. Press Release (Draft)
9. Congressional Letters (Draft)
10. Environmental Assessment (Draft)