

RULEMAKING ISSUE AFFIRMATION

SECY-00-0111

May 19, 2000

FOR: The Commissioners
FROM: William D. Travers
Executive Director for Operations
SUBJECT: FINAL RULE TO AMEND 10 CFR PART 70, DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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PURPOSE:

To seek Commission approval of a final rule amending [10 CFR Part 70](#), "Domestic Licensing of Special Nuclear Material (SNM)," for certain licensees authorized to possess a critical mass of SNM.

SUMMARY:

On July 30, 1999, the Nuclear Regulatory Commission (NRC) published for public comment a proposed rule that would amend its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM (64 FR 41338). After careful consideration of public comments, appropriate modifications to the rule language, and corresponding changes to the Standard Review Plan (SRP), the staff has developed a final rule which: identifies performance requirements for prevention of accidents or mitigation of their consequences; requires affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety necessary to prevent these potential accidents and/or mitigate their consequences; requires the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; requires the safety bases to be maintained, and changes reported to NRC; allows licensees to make certain changes to their safety program and facilities without prior NRC approval; requires reporting of certain events; and requires NRC to perform a backfit analysis under specified circumstances.

BACKGROUND:

The Commission's action on the proposed rule was intended to: maintain safety and protect the environment; enhance public confidence; increase NRC effectiveness, efficiency and realism; and reduce unnecessary regulatory burden. The proposed rule contained risk-informed, performance-based requirements in response to a Petition for Rulemaking (PRM), PRM-70-7, submitted by the Nuclear Energy Institute (NEI), which was published on November 26, 1996. The proposed rule granted the NEI PRM in part and modified the petitioner's proposal. The majority of the proposed modifications to Part 70 were found in a new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These proposed requirements would increase confidence in the margin of safety at operating fuel cycle facilities in accordance with the approach approved by the Commission in its Staff Requirements Memoranda (SRMs) of August 22, 1997, and [December 1, 1998](#).

In developing the rulemaking, the staff sought to achieve its objectives through a risk-informed and performance-based regulatory approach that included (1) the identification of performance requirements for prevention of accidents or mitigation of their consequences, (2) the performance of an ISA to identify potential accidents at the facility and the items relied on for safety to prevent these potential accidents and/or mitigate their consequences, (3) the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed, (4) the maintenance of the safety bases, including the reporting of changes to NRC, and (5) the allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The 75-day public comment period on the proposed rule ended on October 13, 1999. Comments were received from the Environmental Protection Agency (EPA), the Department of Energy ([DOE EXIT](#)), a DOE contractor, uranium fuel fabrication licensees, U.S. Enrichment Corporation, an industry group, and a standards setting group.

In addition, on October 29, 1999, the Counsel to the Nuclear Control Institute (NCI) requested that NRC extend the public comment period for 60 days to allow the staff to fully examine the implications of the criticality accident that occurred at the conversion facility at Tokai-mura, Japan. NRC denied this request. In denying the request, the NRC stated that the proposed 10 CFR Part 70 regulations already contained provisions that require prevention of nuclear criticality accidents, and that it did

not anticipate a need to change these provisions, based on the staff's understanding of the causes of the accident. Since that time, the staff has received a number of reports on the accident as described in [SECY-00-0085](#). The staff continues to conclude that no change in the Part 70 criticality protection provisions, or any other provisions, are needed. In fact, these circumstances reinforce the importance of going forward with the rulemaking which would require maintenance of a risk-informed safety program and keeping the regulator informed of any significant changes in items relied on for safety.

In addition, although the staff did not extend the comment period as a result of this request, the response letter to the Counsel to NCI stated that any comments received in the future would still be considered to the extent practicable. To date, no comments have been received from NCI.

During and following the public comment period, the NRC staff posted revised drafts of the SRP on the NRC web site (i.e., on August 4, 1999, a complete draft SRP was posted, and revised chapters, taking into account comments received, were posted during the period March 16 - April 3, 2000). In addition, the staff held three stakeholder meetings to discuss the SRP (September 14-15, 1999, February 9, 2000, and April 18-19, 2000). The staff also briefed the Commissioners' Assistants on the Part 70 rulemaking in November 1999, and February 2000.

In developing the final rule, the staff carefully reviewed the comments received on the proposed rule and followed the guidance provided by the Commission in its [SRM of July 8, 1999](#). ([Attachment 1](#) provides a description of how the SRM guidance was addressed.)

DISCUSSION:

More than 90 comments (contained in 9 individual letters) on the proposed rule and 200 comments (contained in 13 submittals) on the SRP were submitted to NRC. The specific rule and SRP comments, together with the staff responses to these comments, are tabulated in [Attachments 2](#)  and [3](#) , respectively. The Federal Register notice ([Attachment 4](#) ) also addresses all topics raised by the commenters on the proposed rule.

Substantial modifications were made to the draft SRP to take into account comments received, including comments provided at the public meeting in April 2000. The resulting SRP is provided as [Attachment 5](#). There is general agreement between the NRC staff and the stakeholders on all chapters of the SRP except for Chapter 11, "Management Measures". Although there is general agreement on the importance of the topics addressed in Chapter 11, concerns remain as to the level of detail that would need to be documented and submitted to NRC. The staff plans to meet in an open meeting with stakeholders on June 8-9, 2000, to discuss several examples to be developed by the industry in order for the industry to gain a better understanding of the intended implementation of Chapter 11. Changes to Chapter 11 considered appropriate as a result of the meeting discussions, along with the resolution to other recent comments, will be incorporated into the SRP. Staff will inform the Commission of the results of these activities.

The staff recently met with the ACRS/ACNW joint subcommittee and briefed the subcommittee on the rule with particular emphasis on the ISA aspects. At the conclusion of this briefing, the subcommittee expressed an interest in having additional discussions on staff guidance related to ISAs. The staff plans to meet with the ACRS/ACNW as requested.

The major subject areas for which comments on the proposed rule were received and changes made to the proposed rule text were: (1) the time period for reporting changes made to the ISA summary; (2) backfit; (3) degree of detail in the ISA summary; (4) failure log for items relied on for safety; and (5) extension of period for completion of the ISA. [Attachment 6](#)  describes these issues and their resolution.

The rulemaking package does not contain an enforcement and inspection plan. As noted in [SECY-99-147](#), NMSS staff is developing a revised oversight program for fuel facilities, which was described in [SECY-99-188](#). The revised inspection program is to be more risk-informed and performance-based. In this regard, it has been noted at stakeholder meetings that the ISA, a basic element of the revision to 10 CFR Part 70, will assist the licensees, NRC, and other stakeholders in focusing on risk-significance. The staff will keep the Commission informed of the status of the planned revisions to the oversight process.

Except for the backfit requirement, the new Part 70 provisions would become effective 30 days after the final rule is published in the Federal Register. The staff is developing backfit guidance that will delineate the process and criteria for assessing when additional requirements would be justified on a cost/benefit basis. The backfit requirement would become effective for requirements not covered by subpart H after backfit guidance is published, and would become effective for subpart H requirements for each licensee after NRC approves that licensee's ISA summary pursuant to § 70.66. Within 6 months after the effective date of the rule, existing licensees will be required to submit a plan for performing an ISA. Within 4 years after the effective date of the rule, each licensee will be required to complete the ISA, implement appropriate management measures to ensure items relied on for safety are available and reliable, and submit the ISA summary to NRC for approval. Those reporting requirements which are not linked to the ISA would be implemented on the effective date of the rule. All other subpart H provisions including the change reporting requirements, would be implemented when the ISA is completed, and the ISA summary is submitted, which must be no later than 4 years after the effective date of the rule. To support the implementation of the change process staff will develop guidance.

RESOURCES:

The resources needed to complete this action, including the development of implementing guidance, are in the current budget for FY00 - FY02.

RECOMMENDATIONS:

That the Commission:

1. Approve the "Notice of Final Rulemaking" for publication ([Attachment 4](#) )
2. Certify that the rule, if promulgated, will not have a negative 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:
 - a. The rulemaking will be published in the Federal Register ([Attachment 4](#) 
 - b. The SRP, as modified to reflect the results of the June public meeting and other recent comments, will be placed in the NRC's Public Electronic Reading Room ([Attachment 5](#));
 - c. The ISA Guidance Document will be placed in the NRC's Public Electronic Reading Room ([Attachment 7](#));
 - d. The Environmental Assessment will be placed in the NRC's Public Electronic Reading Room ([Attachment 8](#));
 - e. The regulatory analysis will be placed in the NRC's Public Electronic Reading Room ([Attachment 9](#) 
 - f. 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;
 - g. This rule contains a new information-collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.);
 - h. A press release will be issued.
 - i. The appropriate Congressional committees will be informed. Copies of the Federal Register Notice of final rulemaking will be distributed to all affected licensees. The notice will be sent to other interested parties on request.
 - j. The NRC has determined that this action is not a major rule, under the Small Business Regulatory Enforcement Fairness Act of 1996 and has confirmed this determination with the Office of Management and Budget. This determination will be reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office ([Attachment 10](#) 

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this rulemaking package for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the rule for information technology and information management implications and concurs in the rulemaking.

/RA/

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Attachments:

1. [Disposition of Staff Requirements Memorandum \(SRM\) Issues](#)
2. [Disposition of Public Comments on rule](#) 
3. [Disposition of Public Comments on SRP](#) 
4. [FRN of Final Rulemaking](#) 
5. Standard Review Plan
6. [Major Issues of the rule](#) 
7. ISA Guidance Document
8. [Environmental Assessment](#)
9. [Regulatory Analysis](#) 
10. [Small Business Regulatory Enforcement Fairness Act Forms](#) 

