RULEMAKING ISSUE

(Notation Vote)

October 1, 2004 SECY-04-0178

FOR: The Commissioners

FROM: Luis A. Reyes

Executive Director for Operations /RA/

SUBJECT: REGULATORY SOLUTION FOR 10 CFR PART 71 CHANGE

AUTHORITY FOR DUAL-PURPOSE PACKAGE CERTIFICATE

HOLDERS

PURPOSE:

To present a final resolution for Commission consideration and request Commission approval for publication of a withdrawal notice regarding the implementation of change authority for dual-purpose (storage and transport) package certificate holders, a remaining open issue from the January 2004, 10 CFR Part 71 final rule.

BACKGROUND:

On November 20, 2003, the Commission issued a Staff Requirements Memorandum (SRM-SECY-03-0141) that approved publication of a final rule making numerous changes to 10 CFR Part 71, but that also directed staff to obtain further input from stakeholders to resolve a remaining issue associated with change authority for dual-purpose package certificate holders. The Commission directed staff to propose a final regulatory solution to the Commission for this issue. Based on this direction, the staff developed a plan to engage stakeholders for additional input with respect to issues associated with change authority. The staff's follow-on work is described in SECY-04-0016 - "Plan for Resolving 10 CFR Part 71 Change Authority for Dual-Purpose Package Certificate Holders." The plan consisted of four activities.

CONTACTS: Daniel Huang, NMSS/SFPO

301-415-3381

Mary Adams, NMSS/IMNS

301-415-7249

identified were: (1) issue a discussion paper; (2) hold a public workshop; (3) develop an implementation plan; and (4) propose a regulatory solution. The discussion paper was issued on March 15, 2004, (69 FR 12088) and the public workshop was held on April 15, 2004. The April 15, 2004, public workshop was attended by approximately 100 persons and involved presentations by U.S. Nuclear Regulatory Commission (NRC) staff, as well as roundtable discussions involving representatives from industry, states, and public interest groups. An implementation plan was subsequently developed in June 2004, based on information collected from the public workshop, as well as written comments received from the stakeholders. Written comments were received from the Nuclear Energy Institute (NEI) and the State of Nevada. This Commission paper represents the fourth and final activity pursuant to the plan documented in SECY-04-0016.

DISCUSSION:

The proposed change authority for Part 71 was included in the proposed rule for Part 71 (67 FR 21390) as Subpart I, Type B(DP) Package Approval. The proposed Subpart I would only have been applicable to dual-purpose packages that had already been certified under 10 CFR Part 72 (storage regulations). The proposed rule addressing this issue, 10 CFR Subpart I – Application for Type B(DP) Package Approval, would have created a new type of package certification, designated as a Type B(DP). The proposed Subpart I would have also authorized holders of Type B(DP) certificates to make changes to the package design and procedures without NRC approval under certain conditions. The proposed 10 CFR 71.153 of Subpart I would require the application for a Type B(DP) package to include two parts: (1) a current Part 71 application for a Type B(U) package; and (2) the additional information specifically required for the Type B(DP) packages, including, among other things, a safety analysis report (SAR) that provides an analysis of potential accidents, package response to these potential accidents, and consequences to the public. The proposed change authority was the focus of the second half of the April 15, 2004, public workshop.

The major concern raised by the dual-purpose cask vendors and industry representatives is that the second SAR specified in the proposed Subpart I would impose a substantial cost and burden on them. Unlike current Part 71 standards for Type B(U) packages that are fundamentally route and mode independent, transport routes and population distributions might be needed for the second SAR in order to evaluate potential accidents, package response to these accidents, and consequences to the public. In addition, the accident analyses would be more complicated than the engineering examinations under the existing Part 71 hypothetical accident conditions. The dual-purpose cask vendors and industry representatives believe that it could require significant expenditures on the part of the applicant to produce such an SAR. Some commenters believed that there is a "work-around" for this issue, in that a set of "standard" accidents could be developed. However, this was also recognized as being resource-intensive, in terms of developing guidance. In addition, the dual-purpose cask vendors and industry representatives believe that, because of the lack of guidance on requirements that are new in the proposed Subpart I, NRC review would be time-consuming and thus expensive. The lone endorsement for the implementation of the proposed Subpart I, which came from a consultant for the State of Nevada, who attended the April 15, 2004, public workshop and submitted written comments, also recognized that it would be quite costly to implement the proposed Subpart I and suggested that NRC pay for the development and review costs of the first few "second SARs," to minimize the impact.

Several dual-purpose cask vendors suggested that, by comparison, making changes under the current Part 71 would be a more cost effective and less burdensome path to go forward than the proposed change authority of Part 71 Subpart I. Their experience indicated that, for changes that do not significantly affect the design bases of the package, amendments can often be made in a timely fashion and do not require substantial resource expenditures. This view is consistent with the NRC discussion paper published for the workshop that explained the reasons for not finalizing the change authority in the January rule (69 FR 3632). Furthermore, experience from the dual-purpose cask vendors also indicated that many changes made to a dual-purpose cask under the provisions of 10 CFR 72.48 (the change authority of Part 72), may also be made without prior NRC approval in the current regulatory structure of Part 71, without explicit change authority. This is because much of the information in the transportation package application is not referenced in the Certificate of Compliance (CoC). Only changes that affect the CoC conditions need prior NRC approval, and generally the CoC conditions only reference design drawings, operating procedures, and some maintenance commitments. Design drawings are binding on CoC holders, and need to have sufficient detail to identify the package accurately and to provide an adequate basis for its evaluation. Licensees who put very tight bounds on their design drawings by including a lot of details that are not required limit their flexibility to make changes without an amendment. Thus, it is important for applicants to write applications that focus on the design features necessary to meet the regulatory requirements of Part 71.

In summary, the dual-purpose cask vendors and industry representatives believe that the potential benefits resulting from implementation of the proposed Subpart I do not outweigh the additional costs and burdens. Only one commenter expressed support for the as-proposed rule. There were some comments that suggested alternatives that were outside the proposed rule. Furthermore, as part of the implementation of the proposed Subpart I, the NRC would have to expend significant resources to develop guidance documents on accident analyses, structures, systems, and components important to safety, the change process, and reviews of methodologies used in the design bases. Additionally, the staff resources needed to review an application under the proposed Subpart I would increase with the need to review additional application material.

The current Part 71 certification process provides a framework that allows certificate holders the flexibility to make certain changes without prior NRC approval, in package design, in authorized contents, and in package operations provided the changes do not affect CoC conditions. Therefore, the staff proposes to withdraw the previously proposed change authority under Part 71.

RECOMMENDATIONS:

That the Commission:

1. <u>Approve</u> for publication, in the <u>Federal Register</u>, the withdrawal of proposed Subpart I of 10 CFR Part 71.

2. Note:

- a. To supplement the withdrawal and to better communicate existing flexibility, the staff will develop Interim Staff Guidance (ISG) to inform the NRC staff reviewers and stakeholders about the flexibility that is available under the current provisions of Part 71. An ISG is an addendum to the Standard Review Plan (SRP) for Parts 71 and 72 reviews, which will eventually be incorporated into the SRP. Information provided in the discussion paper, which was issued on March 15, 2004, to facilitate discussions at the April 15, 2004, public workshop, will also be included in this ISG.
- b. That appropriate Congressional committees will be informed of this action.
- c. That a press release will be issued by the Office of Public Affairs when the withdrawal notice is filed with the Office of the Federal Register.

COORDINATION:

The Office of the General Counsel has no legal objection to this proposal.

/RA Ellis W. Merschoff Acting for/

Luis A. Reyes Executive Director For Operations

Attachment:

Federal Register Notice to withdraw Subpart I of Part 71

2. Note:

- a. To supplement the withdrawal and to better communicate existing flexibility, the staff will develop Interim Staff Guidance (ISG) to inform the NRC staff reviewers and stakeholders about the flexibility that is available under the current provisions of Part 71. An ISG is an addendum to the Standard Review Plan (SRP) for Parts 71 and 72 reviews, which will eventually be incorporated into the SRP. Information provided in the discussion paper, which was issued on March 15, 2004, to facilitate discussions at the April 15, 2004, public workshop, will also be included in this ISG.
- b. That appropriate Congressional committees will be informed of this action.
- c. That a press release will be issued by the Office of Public Affairs when the withdrawal notice is filed with the Office of the Federal Register.

COORDINATION:

The Office of the General Counsel has no legal objection to this proposal.

/RA Ellis W. Merschoff Acting for/

Luis A. Reyes Executive Director For Operations

Attachment:

Federal Register Notice to withdraw Subpart I of Part 71

ML041480182 *See previous concurrence

OFC:	SFPO	SFPO	TechEd	SFPO	ADM/RDB	SFPO
NAME:	DHuang*	RLewis*	EKraus*	LCamper*	MLesar*	EWBrach*
DATE:	8/12/04	8/16/04	8/04/04	8/23/04	8/24/04	9/13/04
OFC:	OGC	IMNS	NMSS	DEDMRS	EDO	
NAME:	STreby*	CMiller*	JStrosnider	MVirgilio	LAReyes (EWMerschoff for)	
DATE:	9/10/04	9/16/04	9/23/04	10/1/04	10/1/04	

OFFICIAL RECORD COPY