

# 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. The four activities

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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. Approve for publication, in the Federal Register, 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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN: 3150-AG71

Packaging and Transportation of Radioactive Material;  
Withdrawal of Subpart I

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule: Withdrawal.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is withdrawing a portion of a proposed rule (Subpart I, April 30, 2002; 67 FR 21390) that would have allowed certificate holders for dual-purpose (storage and transport) spent fuel casks, designated as Type B(DP) packages, to make certain design changes to the transportation package without prior NRC approval. The NRC is taking this action because it has received significant comments regarding the cost and complexity to implement the proposed change authority rule.

**EFFECTIVE DATE:** [Insert date of publication.]

**FOR FURTHER INFORMATION CONTACT:** Mary Adams, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7249, e-mail MTA@nrc.gov.

Supplementary Information:

On April 30, 2002 (67 FR 21390), the NRC published in the Federal Register a proposed rule amending NRC's regulations on packaging and transporting radioactive materials to make the regulations compatible with the International Atomic Energy Agency (IAEA) standards. The proposed final rule also proposed changes in fissile material exemption requirements to address the unintended economic impact of NRC's emergency final rule entitled, "Fissile Material Shipments and Exemptions" and addressed a petition for rulemaking (PRM-73-12) submitted by International Energy Consultants, Inc. The Commission also identified eight additional issues for consideration in the 10 CFR Part 71 rulemaking process. One of these NRC-initiated issues was Issue 15, adoption of change authority for dual-purpose package certificate holders. 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, Type B(DP). The proposed Subpart I would also have authorized holders of Type B(DP) certificates to make changes to the package design and procedures without NRC approval under certain conditions.

NRC received substantial comments on the proposed rule, including numerous comments on the proposed Subpart I. The comments on the proposed Subpart I are presented below, with NRC's responses. On January 26, 2004 (69 FR 3698), the NRC published in the Federal Register a final rule amending 10 CFR Part 71. In that final rule, the Commission did not reach a final decision on the issue of change authority for dual-purpose package certificate holders. The NRC determined that implementation of the proposed change authority rule (Issue 15) could result in new regulatory burdens and significant costs, and that certain changes were already authorized under the current 10 CFR Part 71 regulations. The NRC further stated in the Federal Register that additional stakeholder input was needed on the

values and impacts of the change authority rule before it could decide whether to adopt a final rule providing change authority. Subsequently, the NRC issued a discussion paper on March 15, 2004 (69 FR 12088), to facilitate discussions of the change authority rule and held a public workshop on April 15, 2004, with appropriate stakeholders to discuss the same proposed rule. The workshop transcripts are available on the NRC's public web site at [www.nrc.gov](http://www.nrc.gov), under Current Rulemakings, Final Rules and Policy Statements, Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments Rulemaking Text and Other Documents (RIN 3150-AG71).

Information collected from the public workshop, as well as written comments received from the stakeholders, were overwhelmingly against implementation of the change authority rule. In light of the public comments received, the Commission has reconsidered the need for the change authority provided in proposed Subpart I of the proposed rule and has determined to withdraw Subpart I of the proposed rule for the reasons explained below.

The current Part 71 licensing process provides a framework that allows licensees flexibility to make certain changes without prior NRC approval. The licensee can maximize such flexibility by writing Safety Analysis Reports that focus on the design features necessary to meet the regulatory requirements of Part 71. Typically, the NRC Certificate of Compliance (CoC) references design drawings, specification of the authorized contents, operating procedures, and maintenance commitments. These drawings and documents identify the design and operational features that are important for the safe performance of the package under normal and accident conditions. Therefore, the drawings and documents need to be of sufficient detail to identify the package accurately and to provide an adequate basis for its

evaluation. However, when licensees include features that do not contribute to the ability of the package to meet the performance standards in Part 71 in drawings and documents, the licensees limit their flexibility to make changes without prior NRC approval. Furthermore, experience from the stakeholders has indicated that many changes made to a dual-purpose cask under the provisions of §72.48, may also be made without prior NRC approval in the current regulatory structure of Part 71, without explicit change authority.

Implementation of the change authority in the proposed rule, on the other hand, would result in new regulatory burdens and significant costs for both stakeholders and NRC without a commensurate potential benefit. The proposed rule would require the applicant to: perform an independent analysis of potential transportation accidents specific to that design and plans for use; project package responses to “real world” transportation accidents; and determine the consequences to the public from such accidents. It would also require the applicant to perform a documented evaluation to demonstrate that “changes” would not result in the increase of frequency and consequences of potential “real world” transportation accidents or the likelihood and consequences of a malfunction of structures, systems, and components (SSCs) important to safety; or raise the possibility of an unevaluated accident or malfunction. Consequently, the applicant would need information such as the transport routes and population distributions along the transportation routes on which a specific design is intended to be used. Since such information is not readily available, it could require significant expenditures and efforts on the part of the applicant to produce such information. Furthermore, as part of the implementation of the proposed Subpart I, NRC would have to expend significant resources to develop guidance documents on accident analyses, SSCs 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 likely increase significantly with the need to perform reviews and document staff findings in the Safety Evaluation Report (SER) for these additional items.

## **PUBLIC COMMENTS ON THE CHANGE AUTHORITY OF 10 CFR PART 71**

### **Public Comments on the Proposed Rule, April 30, 2002.**

#### **Issue 15. Change Authority for Dual-Purpose Package Certificate Holders**

*Comment.* One commenter opposed NRC's proposal to "harmonize" transport and storage of spent nuclear fuel and fissile materials with "a watered down international standard" . The commenter said that the Type B(DP) package as proposed does not provide an adequate level of public protection from radiation hazards.

*Response.* The NRC acknowledges the commenter's opposition to the proposed rule change. The NRC has decided to withdraw proposed Subpart I for the reasons explained above.

*Comment.* An industry representative voiced support for the change authority that was included in the proposed rule. The commenter added that the quality assurance programs developed under Part 71 were equivalent in effectiveness and caliber to the programs developed under Part 72.

Five commenters expressed their support for the NRC's proposal, but requested that the change authorization process be extended to all packages licensed under Part 71. Two of these commenters suggested reasons why licensees should be allowed to make minor changes independent of the CoC holders.

Another commenter stated that the changes allowed for shipping packages licensed

under Part 72 should also be allowed for those under Part 71.

*Response.* As previously discussed, the proposed change is not being implemented for either dual purpose casks or for other transportation casks.

*Comment.* Seven commenters expressed disapproval of the proposed change authority for dual purpose casks. One commenter stated that even “minor” design changes made by licensees and shippers could impact the safety of casks and that all changes should be subject to full NRC review. One commenter suggested that there would not be sufficient experience based on the part of the CoC holders to implement the responsibility effectively, and another commenter suggested that the rule lacked specificity for adequate implementation and that the rule change would be more effective if each design change were subject to NRC independent inspection. One commenter asserted that the public has a right to know if design changes are being made.

*Response.* The proposed change process is not being implemented for the reasons previously explained.

*Comment.* One commenter expressed concern that transporting dual-purpose containers is going to be complicated, especially in instances when there is no available rail access.

*Response.* The NRC notes that this comment is beyond the scope of this rulemaking.

*Comment.* Three commenters requested clarifications on various aspects of the proposed change authority. One of these commenters asked for clarification on what is meant by "minimal changes" with potential safety consequences. The commenter also asked that NRC include examples as well as seek, and consider, input from State regulatory agencies when amending certificates of compliance.

Another commenter wanted to know if a certificate holder proposing a minor change

would still have to check with the NRC to see if the change was permissible under the proposed change authority. The commenter wanted to know if NRC would be notified before the changes are made. The commenter requested clarification of the procedure for changes under the proposed change authority. The commenter also requested a more detailed explanation of what constitutes a minor design change with no safety significance.

The last commenter wanted to know what types of changes could be made to dual-purpose spent nuclear fuel casks intended for domestic transport. This point was echoed by the first commenter who recommended that NRC establish guidance for determining when a design or procedural change that enhances one cask function might compromise the effectiveness of the other. NRC should ensure that the interrelationship between the storage and transportation effects of cask changes are considered during the review of certificate amendment requests. Furthermore, the first commenter stated that NRC should consider issuing a single certificate of compliance instead of two.

*Response.* The proposed change process is not being implemented for the reasons previously explained.

*Comment.* One commenter noted that the eight criteria used to determine if changes require NRC prior approval were extracted verbatim from Parts 50 and 72 and placed into Part 71. The commenter suggested that these criteria be customized before inclusion in Part 71.

*Response.* The eight criteria used to determine if changes require prior NRC approval are effectively the same as those included in Parts 50 and 72. This motivated the staff to reevaluate how the proposed change process could be implemented and led to the determination that the proposed change process should not be added by this rulemaking as previously discussed.

*Comment.* One commenter noted that a large number of highly radioactive shipments could take place in dual-purpose containers and that these shipments could be destined for a repository. The commenter explained that even minor design changes would affect waste acceptance at the repository.

*Response.* This comment deals with detailed transportation and storage plans/designs that will need to be developed by the U.S. Department of Energy (DOE) in its effort to design, construct, and operate a proposed high level waste repository site and is beyond the scope of this rulemaking.

*Comment.* One commenter expressed support for the design change authority being provided to CoC holders but recommended that the ability to make changes to the transportation design aspects of a dual-purpose package be provided to licensees who use the casks as well. The basis for this recommendation is that the change process included in Part 72 for storage facilities or casks allows licensees to make changes to the storage design without prior NRC approval subject to certain codified tests. Another commenter was concerned that the proposed revisions to change authority would hinder the ability of Part 72 general and specific licensees to effectively manage and control their Dry Cask Storage Program and ensure that changes made in accordance with Part 72 do not impact the Part 71 certification of spent fuel casks.

*Response.* The proposed change process is not being implemented for the reasons previously explained.

*Comment.* Three commenters expressed support for the proposed change authority. One of these commenters asserted that allowing the change authority would allow for more attention to more significant safety issues.

*Response.* These three commenters did not provide a basis for their support of the

proposed rule. The comments did not have the benefit of the additional information in the discussion paper that clarified NRC's view on the proposed rule and the April 15, 2004 workshop discussions. Although these three comments were in support of the proposed change authority, there were also significant concerns raised as indicated in response to other comments. The NRC staff considered all the comments and for the reasons described above, NRC determined that the proposed change process should not be implemented in this rulemaking. The NRC does not agree that the proposed change authority would allow for more attention to significant safety issues because the existing standards of Part 71 would still be required to be demonstrated.

*Comment.* Two commenters suggested improvements on the procedures of the change authority. One stated that the two-year submittal date for application renewal is too long and instead suggested a 30-day requirement. The other commenter stated that the proposed § 71.175(d) change reporting requirements need to allow for a single report to be filed by dual-purpose COC holders to comply with the requirements of Parts 71 and 72, to avoid unnecessary duplication of reports. Both stated that the proposed submittal date of two years before expiration for the renewal of a CoC or QA program is burdensome and should have a submittal date of only 30 days before expiration, as is required under Part 72. One commenter suggested that a CoC holder should be permitted to submit [change process implementation summary] report for both Part 71 and Part 72 designs as one package instead of having to provide two separate reports.

*Response.* The NRC has chosen not to include the proposed change process in the final rule for the reasons previously explained.

*Comment.* One commenter discussed 71/72 SAR's (Safety Analysis Reports) for the change authority. The commenter stated that a single 71/72 SAR for generally certified dual-

purpose systems should also be permitted as an option for CoC holders. The commenter suggested that the rule language should include provisions for submitting updated transportation Final Safety Analysis Reports (FSARs) for casks already certified and having an approved SAR. The commenter suggested that an FSAR Rev. 0 be submitted to replace the last approved transportation SAR within two years of the effective date of the final rule, consistent with the proposed §71.177(c)(6). The commenter stated that the requirement in proposed §71.177(c)(7) for an FSAR update to be submitted within 90 days of issuance of an amendment of the CoC is unnecessary and inconsistent with the requirements under Part 72 for the dual-purpose spent fuel storage casks. The commenter stated that this creates an unnecessary administrative burden on CoC holders by requiring extra FSAR updates. The commenter said that this portion of the proposed rule should be deleted.

*Response.* Regarding the suggestion to permit the submittal of a single SAR for reflecting both the transportation and storage design for a dual-purpose cask, the NRC staff notes that the SAR submittal request is now moot based on the final rule language.

The NRC staff notes that because Subpart I is being eliminated from the final rulemaking, the comment regarding the addition of a provision in the rule language for submittal of SAR updates for those transportation casks already certified is not applicable.

The last comment regarding the requirement for the submittal of an updated FSAR within 90 days of an amendment to the transportation certificate of compliance is not applicable.

*Comment.* One commenter expressed a number of concerns about the proposed change process for dual purpose casks. The commenter questioned the NRC position that the change process be implemented by the CoC holder while the licensee would be most familiar with details such as site-specific parameters affecting preparation, loading, and shipment of Type B(DP) packages. The commenter also noted that it has been unable to convince NRC

that the level of required detail in the FSAR is excessive and would, therefore, require excessive evaluations with procedure changes that could only be addressed by the CoC holder rather than the licensee who is implementing detailed procedures. The commenter added that industry experience with storage procedures clearly demonstrates that the proposed limitation on procedure evaluation against the Part 71 FSAR by the licensee is unworkable.

*Response.* The proposed change process is not being implemented for the reasons previously explained.

#### **Public Comments from Meeting/Workshop April 15, 2004**

*Comment.* One commenter noted that changes can be made under the current Part 71, without coming to the NRC for approval if the changes do not affect the drawings and contents listed in the certificate. Consequently, the commenter suggested that making intelligent SAR drawings and operations chapters appears to be a much better path for going forward than the proposed change authority of Part 71. The commenter also noted that the change authority for Type B(DP) packages included in the proposed Subpart I would add a substantial amount of work to a cask designer and license holder without a commensurate potential benefit. The commenter pointed out that many users of Part 72 products wait until the last minute to buy their products and are under the gun to get them loaded. Furthermore, Part 72 amendment is a rulemaking process that takes a long time. Therefore, change authority is essential for Part 72. The commenter suggested that time is not an issue with Part 71 changes at the present time, or in the near future, because of the lack of activities in spent fuel transportation. Thus, there is time to deal with any discrepancies in the transport certificates that the licensees pick up either in the course of design changes or manufacturing.

*Response.* NRC acknowledges the commenter's opinion about the proposed change authority of Part 71 which provide support for the NRC's decision to withdraw the proposed

## Subpart I.

*Comment.* Four commenters voiced their support for the concept of change authority. Two commenters suggested that the change authorization process be extended to all packages licensed under Part 71. One commenter, who is an industry representative, suggested that the change authority should be based on existing Part 71 criteria rather than on a new supplemental set of Part 71 criteria. In a subsequent letter, dated April 30, 2004, the industry representative informed NRC that the industry does not endorse NRC's proposed change process for Part 71 because the limited change ability, and the required additional FSAR, as included in the proposed Subpart I, would add significant cost and very little benefit to the industry. The industry representative encouraged NRC to develop a change process for Part 71 that is based on the existing regulatory safety criteria of Part 71 and offered to work with NRC cooperatively, for such an effort.

*Response.* NRC acknowledges the commenter's support for the concept of change authority; however, the proposed change process is not being implemented as described above either for dual-purpose casks or for other transportation casks.

*Comment.* One commenter voiced support for the cask-specific, mode-specific, and route-specific approach to safety analysis included in the proposed Subpart I. The commenter noted that the analysis is presently one-sided, for dual-purpose casks, because licensees are required to consider all potential accidents and their consequences for storage; however, the likelihood and consequences are not considered for transportation. The commenter viewed the proposed Subpart I, §71.153, which requires a probabilistic risk analysis for transportation, to be the instrument to correct this imbalance. The commenter suggested that this approach would not only be extremely useful for emergency planning purposes, but also would be helpful in avoiding populated areas, tunnels, high bridges, routes with high accident rates, etc., or to

demonstrate that dual-purpose casks can withstand potential accidents along these routes. The commenter further suggested that dual-purpose casks certified as a result of this approach would greatly enhance public confidence in the nuclear industry which, in turn, would also benefit the DOE as the owners and/or shippers of these casks to Yucca Mountain.

*Response.* NRC acknowledges the commenter's support for the proposed change authority of Part 71 and understands that an independent accident analysis specific to designs could have public-confidence benefits. However, NRC disagrees with the commenter that the analysis is one-sided for dual-purpose casks. Dual-purpose casks must also meet performance requirements specified in Part 71 for packaging and transportation of radioactive material. Among the performance requirements, dual-purpose casks must be capable of withstanding the mechanical and thermal loading imposed by normal and accident conditions and still meet specified acceptance criteria. These conditions have been internationally accepted and have been shown to encompass spent fuel casks performance in severe accidents. The safety record associated with Part 71 for the domestic transportation of spent fuel is exemplary - approximately 1,300 shipments of civilian fuel and 920,000 miles without an accidental radioactive release. Nonetheless, NRC continually examines the transportation safety programs. Furthermore, the Type B(DP) package approval in the proposed rule presented only an option for transportation. That is, other Type B packages would still be permitted for spent fuel transportation, and those packages would not require the mode and route specific accident analysis in proposed Subpart I. As for comments regarding emergency planning and avoiding populated areas, tunnels, high bridges, routes with high accident rates, etc., the U. S. Department of Transportation (DOT) regulates routing for hazardous material transportation, including radioactive materials.

*Comment.* One commenter requested that the decision for the final rule regarding

Part 71 change authority for dual-purpose package certificate holders be delayed for a period of six to nine months. The commenter cited the likely influences, regarding the cask selection choices, by: (1) the DOE Yucca Mountain transportation plan; (2) final status of the license for the Private Fuel Storage facility in Utah; and (3) the staff recommendations regarding the NRC package performance study (PPS), as reasons for the request.

*Response.* NRC acknowledges the request for delaying the final rule regarding the change authority of Part 71; however, potential cask selection choices would not impact the Commission's decision to withdraw the proposed rule.

*Comment.* One commenter wanted to know if all dual-purpose casks have to have a Type B(DP) approval, or whether they still can get a Type B(U) approval? The commenter also wanted to know if someone does get a Type B(DP) approval, could another person with basically the same design get a Type B(U) approval?

*Response.* No responses to the commenters questions are needed given NRC's decision to withdraw the Type B(DP) approval process.

*Comment.* Two commenters noted that there is a great deal of flexibility in the current Part 71 and wondered if NRC is planning to put out additional guidance to alert the designers to the flexibility that is available.

*Response.* NRC acknowledges the commenters' recommendation regarding the current flexibility in Part 71 and agrees with the potential benefit of guidance on flexibility and making changes for Type B packages under Part 71. NRC understands that it would be helpful to describe and articulate the way that applications should be prepared to allow this flexibility. This includes identifying areas of flexibility, the kinds of things that are flexible, where we have seen problems, and where there are areas of over-commitment in the applications. Although no decision has been made on the method of communication to be used to inform the

stakeholders about the flexibility that is currently available under Part 71, the staff would like to point out that several existing documents provide some of this guidance. Regulatory Guide 7.9, “Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material,” NUREG/CR-5502, “Engineering Drawings for 10 CFR Part 71 Package Approvals,” and NUREG/CR-4775, “Guide for Preparing Operating Procedures for Shipping Packages,” are three examples that provide guidelines for preparing applications for package approval under the current Part 71.

*Comment.* One commenter expressed concern that having to do a second safety analysis report, as proposed in Subpart I, to set up a whole set of criteria and identify another set of accident scenarios, probabilities, and consequence analyses, etc., is going to be very burdensome on the front end. The commenter cautioned that a lot more questions will be raised, rather than answered, if the industry goes down the path of having everyone develop their own accident scenarios, probabilities, and consequence assessments. The commenter suggested that the cost associated with doing a second SAR may be more expensive than doing an SAR under the current Part 71, because the regulations under the current Part 71 are very well defined and the industry knows exactly what it has to address. The commenter further suggested that it will take a lot of license amendments, under the current Part 71, to get a payback on the additional cost for second SAR approval.

*Response.* NRC acknowledges the commenter’s information about potential burdens and costs that the proposed rule could impose on stakeholders.

*Comment.* One commenter suggested that the change authority included in the proposed Subpart I would not benefit existing packages; however, it might benefit new applications because they can build in enough flexibility in the drawings of the new applications.

The commenter also called for an industry forum to develop a set of accident scenarios that will be binding for everybody.

*Response.* The NRC has decided to withdraw the proposed rule for the reasons previously explained.

*Comment.* Two commenters noted that, based on their respective experience in Part 72, the percentage of changes made, under §72.48, that require a corresponding change to the Part 71 Certificate of Compliance, will be very low.

*Response.* NRC acknowledges the commenter's experience about changes that were made, under §72.48, for dual-purpose casks, that would still require a Part 71 Certificate amendment.

*Comment.* One commenter wanted to know whether changes can be made, under the regular Part 71 approval, without coming to NRC for amendments, if the same changes were first made under the change authority of Part 71, for Type (DP) packages.

*Response.* This comment is now moot, given NRC's decision to withdraw the proposed Subpart I.

*Comment.* One commenter used an example of minor design change to illustrate what would happen under the current Part 71 and what it might look like under the proposed Subpart I. Based on the scenario discussed, the commenter predicted that no one will be using the proposed Subpart I because a minor design change does not appear to be a particularly time-consuming or costly operation under the current Part 71, as compared to the proposed Subpart I.

*Response.* NRC acknowledges the comparison about making design changes under the current Part 71, and the proposed Subpart I.

*Comment.* One commenter suggested that a well developed full-scale cask testing program would address cask performance issues and eliminates the need to do a very detailed SAR, as proposed in Subpart I.

*Response.* NRC acknowledges the recommendation of using full-scale tests for certification, however, Part 71 does not require full-scale tests for certification. It is the applicant's decision as to whether to use full-scale tests, scale model tests, or analyses, for certification. Therefore, this comment is beyond the scope of this rulemaking.

*Comment.* One commenter wanted to know whether separate certificates are required for a common design with different sizes and weights.

*Response.* Under the current Part 71, variations in design like that are handled under a single certificate. They would be evaluated by looking at bounding configurations.

*Comment.* Four commenters suggested that the proposed Subpart I will not work unless NRC were to provide detailed guidance, developed in consultation with affected stakeholders, on the methods, data, and assumptions to be used in such safety analyses. NRC should not expect individual applicants to have to take that responsibility. One commenter suggested the NRC Modal Study and another suggested NUREG/CR 6672, "Reexamination of Spent Fuel Shipment Risk Estimates," as good representative models of the types of accident analyses that the applicants may want to consider. One commenter cautioned that the standardized accident analysis may not be applicable to an applicant who only uses casks for localized shipments.

*Response.* NRC understands that it is ineffective, inefficient, and possibly confusing to have many different groups and entities creating accident analyses, predicting transport accident probabilities for individual designs. This supports NRC's decision to withdraw the proposed Subpart I.

*Comment.* Two commenters noted that the change authority would not benefit them during the next few years because the spent fuel transportation program is not active at the present time nor expected to be, in the near future. Consequently, most of the current Part 71 amendment requests, rather than dealing with design changes, are dealing with upgrade contents and adding contents to the existing packages, which would not be benefitted by the change authority.

*Response.* NRC acknowledges the commenter's opinion that the proposed change authority of Subpart I lacked near-term benefit.

*Comment.* One commenter, associated with several utilities that store fuel in dry casks at this time, expressed disapproval of paying for the implementation of the change authority without seeing any benefit to the utilities. The same commenter also questioned about paying for the implementation of the change authority while the benefit goes to the public relations for Yucca Mountain Project, as suggested by another commenter.

*Response.* No response to the commenter is needed, given NRC's decision to withdraw the proposed Subpart I.

*Comment.* One commenter noted that the greatest cost for preparation of a SAR associated with the proposed Subpart I would likely occur for the first cask analyzed under the new requirements. The commenter suggested that such cost might appropriately be borne by NRC as part of the PPS. The commenter also suggested that, for those casks to be used for shipments to Yucca Mountain, the cost might appropriately be borne by DOE.

*Response.* No response to the commenter is needed, given NRC's decision to withdraw the proposed Subpart I.

Dated at Rockville, Maryland, this \_\_\_\_\_ day of \_\_\_\_\_, 2004.

For the Nuclear Regulatory Commission.

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Annette L. Vietti-Cook,  
Secretary of the Commission.