

U.S. NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

Regulations for the Safe Transport of Radioactive Material; Public Meeting

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Advance notice of public meeting.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Transportation (DOT) are convening a workshop with an opportunity to discuss any operational concerns for implementing the recently revised transportation regulations in 10 CFR Part 71 and 49 CFR Parts 171 - 178. Part of this workshop will include discussions to obtain a path forward on the portion of the proposed rule concerning 10 CFR Part 71 change authority for dual-purpose certificate holders that was not included in the final rule.

**DATES:** The workshop will be held on April 15, 2004, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The workshop will be conducted at the NRC Auditorium, Two White Flint North, 11545 Rockville Pike, Rockville, MD, 20852.

**FOR FURTHER INFORMATION CONTACT:** David Pstrak, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-8486; email: [dwp1@nrc.gov](mailto:dwp1@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

## Background

On January 26, 2004, the Nuclear Regulatory Commission (NRC) published a final rule (69 FR 3632) that amended the domestic transportation regulations to make them compatible with the 1996 Edition of the International Atomic Energy Agency standards, and to codify other requirements. NRC coordinated this rulemaking and final rule publication with the Department of Transportation (DOT) to ensure that consistent regulatory standards were maintained between NRC and DOT radioactive material transportation regulations, and to ensure joint publication of the final rules. The DOT also published its final rule on January 26, 2004 (69 FR 3632). Both rules become effective on October 1, 2004. During previous rulemakings, both agencies recognized that implementing new requirements often led to questions on specifically what was expected or how a new regulation was to be exercised. To foster an open dialogue with a view towards understanding where uncertainties exist regarding the new requirements, NRC and DOT are seeking views during this open forum.

On April 30, 2002, the NRC published a proposed rule for a major revision of 10 CFR Part 71, Packaging and Transportation of Radioactive Material (67 FR 21390). Among other items, the proposed rule included a set of provisions that would allow certificate holders for dual-purpose (storage and transport) spent fuel casks, designated as Type B(DP) packages, to make certain changes to the transportation package without prior NRC approval. When the final rule was issued on January 26, 2004 (69 FR 3698), the change authority provisions were not adopted. The NRC staff determined that implementation of this change could result in new regulatory burdens and significant costs, and that certain changes were already authorized under current Part 71 regulations. The NRC concluded that additional stakeholder input was needed on the values and impacts of this change before deciding whether to adopt a final rule providing change authority. The following background paper will be used to guide the discussion during the April 15, 2004, workshop.

**DISCUSSION PAPER**  
**10 CFR PART 71 CHANGE AUTHORITY**

Purpose

The purpose of this Discussion Paper is to identify additional input stakeholders may wish to provide with respect to the values and impacts of the proposed rule regarding 10 CFR Part 71 change authority for dual-purpose package certificate holders.

Plan for Resolution

This Discussion Paper is being issued as the first step in addressing concerns identified with the implementation of the change authority as proposed in 10 CFR Part 71. This Discussion Paper identifies specific information that the staff feels will be useful in adequately evaluating the values and costs of implementing the change authority contained in the proposed rule. The staff plans to hold open, public discussions with stakeholders, to collect and evaluate the information, and to then propose a resolution to the Commission. The resolution will consist of issuing a final rule or withdrawing the change authority proposal.

Provisions of the Proposed Rule

The proposed 10 CFR Part 71 established a new Subpart I for Type B(DP) packages, and other related and conforming provisions. Subpart I specified requirements for applying for a Type B(DP) package approval, the contents of the application, and the package description and evaluation. The proposed § 71.153 would require the application for a Type B(DP) package to include two parts. The first part, specified in § 71.153(a), is a package application which is the same as the application requirements currently in effect for a Type B(U) package, including essentially the same package evaluation and performance standards. The second part is a new safety analysis report that among other things includes "an analysis of potential accidents, package response to these potential accidents, and any consequences to the public." It is this second part, the "safety analysis report" as described in § 71.153(b), and the associated

potential accidents and consequences, that would introduce additional, new requirements for the Type B(DP) packages.

The safety analysis report is the document that would be used to evaluate changes that could be made to the package design or operation without prior NRC approval. The safety analysis report would include the identification and evaluation of potential accidents, which are not necessarily limited to the hypothetical accident conditions that are currently used in Part 71. It was envisioned that the safety analysis report would develop an inclusive and rigorous identification and evaluation of potential accidents. Accidents to be considered could address both external natural events and man-induced events. Man-induced events could include transportation accidents and other accident types. It was also envisioned that accident probabilities would be established, which is a departure from the existing Part 71 hypothetical accident conditions. In this regard, the safety analysis report and its accident analysis are similar to the use of those terms in 10 CFR Part 72, the regulations that pertain to spent fuel storage casks.

The consequence evaluation could also include other aspects not embodied in the current Part 71 regulatory framework. For example, release limits for accident conditions are specified in the current regulations, and not dose limits. For the new safety analysis report, the identification of maximum exposed individuals and populations may need to be addressed in the context of the transportation of the casks. Environmental consequences, including pathway analyses, could also be required. Transport routes and population distributions may be needed for the evaluation, unlike current Part 71 standards that are fundamentally route and mode independent.

Type B(DP) package certificate holders would be authorized to make certain changes to the package design and operations based on the provisions in § 71.175(c) of the proposed rule. The change authority would be tied to the safety analysis report required by § 71.153(b). Table 1 compares the proposed provisions with the current rule with respect to evaluations and information that may be required in a package application. The table also identifies the type of information that may be needed in order to evaluate changes made under the provisions of § 71.175(c).

TABLE 1

**COMPARISON OF INFORMATION AND EVALUATIONS  
REQUIRED BETWEEN TYPE B(DP) AND TYPE B(U) PACKAGES**

<b>Provisions of the Proposed Rule for Type B(DP) Package Under Subpart I</b>	<b>Applicable Sections under Proposed Subpart I</b>	<b>Type B(DP) Package</b>	<b>Type B(U) Package</b>
Application for Package Approval	71.153(a)	yes	yes
Meets Package Approval Standards Under Subparts E	71.153(a)(2), 71.157	yes	yes
Meets Performance Standards Under Subparts F	71.153(a)(2), 71.157	yes	yes
Meets Quality Assurance Standards Under Subparts H	71.153(a)(3), 71.159	yes	yes
Demonstrate Safe Use of Package	71.153(b)(2)	yes	no
Evaluate Potential Accidents, Package Response, and Consequences to Public	71.153(b)(3)	yes	no
Justification for At Least 20 Years Usage	71.153(b)(4)	yes	no
Licensing Period for CoC	71.163	up to 20 years	typically 5 years
FSAR	71.177(a)(1) & (2)	yes	no
Periodic Updates of FSAR	71.177	yes	n/a
Maintain Record of Changes	71.175(d)	yes	n/a
Submit Reports of Changes & Summary of Evaluation	71.175(d)(2)	yes	n/a

Provisions of the Proposed Rule for Type B(DP) Package Under Subpart I	Applicable Sections under Proposed Subpart I	Type B(DP) Package	Type B(U) Package
OK for International Transportation		no (not recognized under IAEA regulations)	yes
NRC Approval Needed for Changes in the Terms, Conditions, or Specifications in CoC	71.167, 71.175(c)(1)(i)	yes	yes
Identify Potential Accidents that Will be Evaluated	71.153(b)(3), 71.175(c)(2)	yes	no
Provide Frequency of Occurrence of an Accident	71.175(c)(2)(i)	yes	no
Evaluate Consequence of an Accident	71.175(c)(2)(iii)	yes	no
Evaluate Whether Changes Will Create Possibility of an Accident of Different Type	71.175(c)(2)(v)	yes	no
Establish SSC Important to Safety	71.175(a)(3)(i) & (ii)	yes	no
Provide Probability of SSC Malfunction	71.175(c)(2)(ii)	yes	no
Evaluate Consequence of SSC Malfunction	71.175(c)(2)(iv)	yes	no
Evaluate Whether Changes Will Create Different Result of SSC Malfunction	71.175(c)(2)(vi)	yes	no
Define Design Basis Limit for a Fission Product Barrier	71.175(c)(2)(vii)	yes	no

Provisions of the Proposed Rule for Type B(DP) Package Under Subpart I	Applicable Sections under Proposed Subpart I	Type B(DP) Package	Type B(U) Package
Evaluate Whether Changes Will Exceed Design Basis Limit for a Fission Product Barrier	71.175(c)(2)(vii)	yes	no
Identify Method of Evaluation Used in Establishing the Design Basis	71.175(a)(2)	yes	no
Determine Whether Change is a Departure From the Methods of Evaluation Described in FSAR	71.175(c)(2)(viii)	yes	no

#### Concerns with Implementation Identified by NRC Staff

Section 71.153(b) of the proposed rule states that an application must include a safety analysis report describing an analysis of potential accidents, package response to these potential accidents, and any consequences to the public. This provision departs from the standard Part 71 package application (as described in § 71.153(a)) in that an applicant must now assess potential accidents and their consequences to the public from these accidents. Similar to Part 72 accident analysis, the accidents to be evaluated could include natural and man-made phenomena, but in the context of truck, rail, or vessel transport activities. The types of information needed for the accident analysis may include population densities by route; highway, vessel, and railway accident rates; and cask and vehicle performance in collisions and fires. This information may not be readily available, and could require significant expenditures for both applicants to produce this information and for NRC to develop guidance documents and review the information. Consequences to the public may include radiological and non-radiological consequences, and may include environmental assessments of potential releases of radioactivity. In addition, the information may require identification of specific routes and modes of transport, unlike current package approvals. It is noted that this information would be required in addition to the package application described in § 71.153(a).

### Changes Currently Authorized Under Part 71

Coupled with these concerns, staff recognized that the regulatory structure of Part 71 already allows certain changes to the package without prior NRC approval. For transportation packages, the NRC approves the package design, and the Certificate of Compliance is the approval document that specifies the design (including packaging and radioactive contents) and package operations that are necessary for safe transport. Typically the Certificate of Compliance includes these essential elements: Specification of the design by reference to the design drawings, specification of the authorized contents, and reference to documents that relate to the use and maintenance of the packaging and to the actions to be taken before shipment. 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. Features that do not contribute to the ability of the package to meet the performance standards in Part 71 are not necessarily included as conditions in the Certificate of Compliance. In general, changes to the design or operations that are not conditions of the Certificate of Compliance must be evaluated to assure that they do not affect safety but do not require prior NRC approval.

The staff believes that many changes made to a dual purpose cask under the provisions of 10 CFR 72.48, may also be made without prior NRC approval in the current regulatory structure of Part 71, without explicit change authority. Changes to the conditions in the Part 71 Certificate of Compliance would require prior NRC approval, even for Type B(DP) packages. Therefore staff concluded that, considering the development of the new information in a safety analysis report as described in the proposed § 71.153(b), and with the existing ability to make certain changes to the package design and operation without prior NRC approval, the benefits of implementation of the new rule may not outweigh the costs.

### Input Invited From Stakeholders

To assist staff in estimating the values and impacts of implementation of the proposed rule, staff is inviting stakeholders to provide certain information. Specifically, staff is seeking estimates of the costs associated with development of a safety analysis report evaluating potential accidents, package response, and consequences to the public. Estimates are also needed with respect to the savings that could result from exercising the change authority, for

example, the numbers and types of amendments that would not need to be prepared and reviewed. A set of questions has been developed to guide stakeholders in providing this information. The questions are listed in the attachment to this paper. In addition, stakeholders may provide any other relevant information that they believe could be useful in providing staff with a factual basis for evaluating the values and impacts of the proposed rule.

NRC staff is planning a workshop to be held on April 15, 2004, to discuss the impact of the revised 10 CFR Part 71. As part of the workshop, the staff plans to hold a session devoted to the proposed change authority rule. The staff plans to make a presentation that explains the proposed rule and changes authorized under the current Part 71 regulations. Stakeholders are invited to participate by providing the requested information in written form to be collected at the workshop and in open workshop discussions.

## **PART 71 CHANGE AUTHORITY QUESTIONS**

To facilitate dialogue at the April 15, 2004, meeting, NRC staff prepared the following questions. In addition, stakeholders are welcome to provide written information to the contact above. Written information is requested by April 30, 2004. Anything received after that date will be considered only if practicable. NRC will consider stakeholder comments in identifying a regulatory solution. NRC staff is requesting fact-based input regarding the costs and benefits associated with the proposed change authority. It is requested that the information provided be as specific as practical, with identification of actual experiences, if applicable.

### **Implementation of Proposed Change Authority Rule**

How would Certificate Holders address the new requirements?

How would potential accident scenarios be developed?

How would accident frequencies be determined?

How would consequences be evaluated (address potential releases, populations exposed, environmental pathways)?

How would modes of transport and transportation routes be identified and considered in the accident and consequence analysis?

- How would package suitability for a period of twenty years be demonstrated?
- How would structures, systems and components (SSCs) be determined and identified in the final safety analysis report (FSAR)?
- How would the probability of SSC malfunctions be determined?
- How will the design basis limit for a fission product barrier be defined?
- How will the methods of evaluation used in the FSAR be determined and identified?
- How will the changes made under the proposed rules be tracked, documented, and controlled?

### **Costs of the Proposed Change Authority Rule**

- What are the costs of developing an application containing the requirements of 71.153?
- What guidance documents would be needed from NRC?
- What level of NRC staff review of the Type B(DP) package application would be anticipated?
- What are the costs in preparing FSAR updates, including the basis for changes made under 71.175?

### **Benefits of the Proposed Rule**

- How many certificate amendments would be saved using the change authority (quantify in terms of numbers and complexity)?
- What operational or time savings would result from change authority?
- What other benefits are anticipated (quantify if possible), such as cost of NRC review, minimizing regulatory uncertainty, schedule delay?

### **Changes Made Under Change Authority in 10 CFR 72.48 that Relate to Part 71**

- What is the stakeholder experience with actual changes made under 72.48 (numbers, types, complexity)?
- How many of the changes made under 72.48 would require a corresponding change to the Part 71 Certificate of Compliance (numbers, types, and complexity)?
- What changes (types and number) that were made under 72.48 would still require a Part 71 Certificate amendment considering the ability to use the proposed Part 71 change authority?

**Changes Desired Under Subpart I**

Identify types of changes that are considered beneficial that would fall under the change authority.

Dated at Rockville, Maryland, this \_\_\_\_9th\_\_\_\_ day of March 2004.

For the Nuclear Regulatory Commission

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/RA/  
David W. Pstrak  
Transportation and Storage Project Manager  
Office of Nuclear Material Safety and Safeguards

