



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 19, 2004

SECRETARY

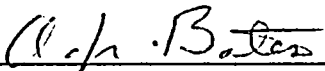
COMMISSION VOTING RECORD

DECISION ITEM: SECY-04-0178

TITLE: REGULATORY SOLUTION FOR 10 CFR PART
71 CHANGE AUTHORITY FOR DUAL-PURPOSE
PACKAGE CERTIFICATE HOLDERS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of November 19, 2004.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.



Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-04-0178

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X					11/16/04
COMR. McGAFFIGAN	X				X	11/12/04
COMR. MERRIFIELD	X				X	11/10/04


COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on November 19, 2004.

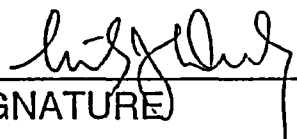
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN DIAZ
SUBJECT: **SECY-04-0178 - REGULATORY SOLUTION FOR 10
CFR PART 71 CHANGE AUTHORITY FOR DUAL-
PURPOSE PACKAGE CERTIFICATE HOLDERS**

Approved xx  Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:
None.



SIGNATURE
11/16/2004

DATE

Entered on "STARS" Yes No _____

NOTATION VOTE

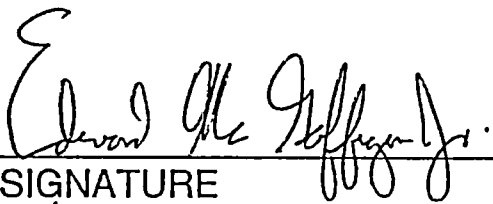
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-04-0178 - REGULATORY SOLUTION FOR 10
CFR PART 71 CHANGE AUTHORITY FOR DUAL-
PURPOSE PACKAGE CERTIFICATE HOLDERS**

Approved Disapproved Abstain

Not Participating

COMMENTS: *See edits to FR.*



SIGNATURE
November 12, 2004

DATE

Entered on "STARS" Yes No

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, 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 ^{generally} ~~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 ^{non-safety related} 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

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. *even if this proposal were finalized, have resulted in have been*

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. X

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-

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^s support for the NRC's decision to withdraw the proposed

X

NOTATION VOTE

RESPONSE SHEET


TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-04-0178 - REGULATORY SOLUTION FOR 10
CFR PART 71 CHANGE AUTHORITY FOR DUAL-
PURPOSE PACKAGE CERTIFICATE HOLDERS**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.



SIGNATURE

DATE *11/10/04*

Entered on "STARS" Yes No

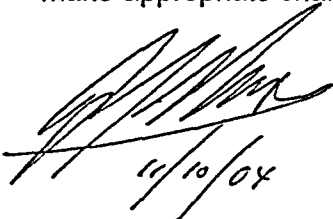
Comments from Commissioner Merrifield on SECY-04-0178:

I approve the staff recommendations in SECY-04-0178 concerning the proposed rulemaking for 10 CFR Part 71 dual-purpose package certificate holders. Specifically staff may withdraw the proposed rulemaking and expeditiously develop Interim Staff Guidance to inform the NRC staff reviewers and stakeholders about the flexibility available under the current provisions of Part 71. I approve the staff recommendations because I believe that it is the most sensible approach to address these issues at this time. However, I believe the staff could have done a better job initially in identifying a regulatory solution to this activity.

The draft rule developed by the staff would require certificate holders to conduct all the analysis currently required under Part 71 plus a fairly extensive and expensive analysis under the proposed rulemaking so that some day they may make minor changes to the cask design without prior NRC approval. Under these conditions, it is ludicrous to assume any licensee would desire to take advantage of the proposed rule because the huge burden to implement this provision of the regulations would far outweigh the small regulatory relief that compliance with the rule would have brought.

The proposed rule developed by the staff uses standards developed for power reactors (10 CFR 50.59) and ISFSIs (10 CFR 72.48). These facilities, once constructed, represent fixed sites, which establishes boundary conditions on any accident analysis. However, staff is now attempting to use these standards for transportation casks, which can be shipped anywhere, and there are essentially no boundary conditions on the accident analysis. This is equivalent to attempting to put a square peg in a round hole. I would have expected the staff to suggest a more innovative approach to address a transportation system with appropriate boundaries on the accident analysis. I would have preferred that the staff consider other alternatives instead of implying that this model was the only regulatory approach for approving design changes without prior NRC approval. For example, staff could have considered significant reductions in margins to safety based on changes to release rates for the transportation cask (which is independent of the transportation route) as opposed to dose (which is dependent on the transportation route). If the NRC can approve a certificate of compliance by a methodology which is independent of the transportation route, there should be an acceptable methodology for approving changes to the certificate under limited circumstances without prior NRC approval which is also independent of the transportation route. Nevertheless, I recognize that implementing such a novel approach may not be the best use of agency resources, particularly if the proposed alternative by the staff can be implemented fairly quickly without rulemaking and would provide a reasonable benefit to the certificate holder.

Finally, the characterization of the industry comments after the last workshop as described in the Commission paper is considerably different than the description of the industry comments provided in the proposed Federal Register Notice for withdrawing the rulemaking. Staff should make appropriate changes in the draft Federal Register Notice.



11/10/04