



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

November 19, 2003

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-03-0141

TITLE: FINAL RULE TO REVISE 10 CFR PART 71 TO
BE COMPATIBLE WITH IAEA
TRANSPORTATION SAFETY STANDARDS
[TS-R-1] AND MAKE OTHER NRC-INITIATED
CHANGES

The Commission (with Chairman Diaz and Commissioner McGaffigan agreeing and Commissioner Merrifield agreeing in part and disagreeing in part) approved the final rule as noted in an Affirmation Session and recorded in the Staff Requirements Memorandum (SRM) of November 19, 2003.

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

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook".

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-03-0141

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	10/23/03
COMR. McGAFFIGAN	X				X	10/1X/03
COMR. MERRIFIELD	X	X			X	10/30/03

COMMENT RESOLUTION

In their vote sheets, Chairman Diaz and Commissioner McGaffigan approved and Commissioner Merrifield approved in part and disapproved in part the final rule as noted in an Affirmation Session and reflected in the SRM issued on November 19, 2003.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Chairman Diaz
SUBJECT: **SECY-03-0141 - FINAL RULE TO REVISE 10 CFR
PART 71 TO BE COMPATIBLE WITH IAEA
TRANSPORTATION SAFETY STANDARDS [TS-R-1]
AND MAKE OTHER NRC-INITIATED CHANGES**

Approved ^{w/comments} xx *ew* Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:

See attached comments.

Ch. J. ...
SIGNATURE

Oct 23, 03
DATE

Entered on "STARS" Yes No _____

COMMENTS OF CHAIRMAN DIAZ ON SECY-03-0141

I approve publication of the final amendments for 10 CFR Part 71. I commend staff for completion of a difficult task that included identification of needed changes in NRC's transportation regulations, as well as evaluation of IAEA's Transportation Safety Standards (TS-R-1), and close coordination with the Department of Transportation to ensure that consistent regulatory standards are maintained between NRC's Part 71 and DOT's Hazardous Materials Regulations.

Prior to publication, the Federal Register Notice should be revised to incorporate the following changes, most of which are important to clear communication with the public and stakeholders:

1. The responses under "Adequacy of NRC Regulations and Rulemaking Process" need to be revised to more carefully distinguish between the meaning and significance of "**biological** effects" and "**health** effects."
2. The FRN should not include statements that are not evidence-based, i.e., can not be supported by data, peer reviewed journals, etc., e.g., on page 26 the statement "Recently, concern has been expressed that long-term exposure to low levels of radiation may be more dangerous than short-term exposures to high levels" should be deleted based on the following statement that ""However, there is no epidemiology data, published in peer reviewed journals, to support this concern."
3. References for significant scientific conclusions that have appeared in peer-reviewed scientific journals should be provided, e.g., the statement "No birth defects or genetic disorders among the children born to atomic bomb survivors from Hiroshima and Nagasaki have been observed at low doses of radiation (<25 rad)" on page 26.
4. The FRN should be carefully screened for phrases and terms that have no clear meaning, e.g., what is meant by "**mildly** radioactive materials" on page 24 and "any **undue** increase in exposure" on page 28.
5. The FRN should be carefully reviewed to ensure that it contains the most up-to-date information, e.g., on page 37 the response to a comment on which countries have already adopted the proposed IAEA guidelines is based on a September 2002 survey.
6. The FRN should be reviewed to make sure that it does not leave the reader searching for information, e.g., on page 89 it states that " while some revised A_1 and A_2 values are higher and some are lower, the potential dose following an accident is the same as with the previous A_1 and A_2 values " but the reader is not provided with the dose upon which the values are based.

Staff should keep the Commission informed of future changes to the IAEA's Transportation Safety Standards, while they are still under discussion, in order to provide the Commission an early opportunity to provide staff input on these changes.



AFFIRMATION ITEM

RESPONSE SHEET

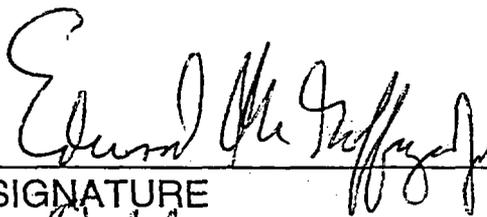
TO: Annette Vietti-Cook, Secretary
FROM: Commissioner McGaffigan
SUBJECT: **SECY-03-0141 - FINAL RULE TO REVISE 10 CFR
PART 71 TO BE COMPATIBLE WITH IAEA
TRANSPORTATION SAFETY STANDARDS [TS-R-1]
AND MAKE OTHER NRC-INITIATED CHANGES**

Approved ^{w/comments} X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments, and edits.



SIGNATURE
October 31, 2003

DATE

Entered on "STARS" Yes X No _____

Commissioner McGaffigan's Comments on SECY-03-0141

I approve the publication of the final amendments to 10 CFR Part 71. I agree with Chairman Diaz that the staff should be complimented on completing this rulemaking. I also agree with the Chairmans' edits to the Federal Register Notice and have attached a few edits of my own.

After completing this rulemaking, the staff should continue to focus some attention on Issue 2 - Radionuclide Exemption Values. The paper suggests that the Commission consider an option of extending the 10 times exemption multiple provision to all natural material containing NORM and ore shipments regardless of the intended use following processing. As it stands now this exemption is only for NORM and ores that are not intended to be processed for use of their isotopes. I agree with the staff that implementing this exemption for all NORM regardless of intended use is appropriate. I support the staff moving forward and discussing this option with DOT. I realize that this change can not be included in this rulemaking, but the staff should pursue making this change in the near future.

I also agree with Commissioner Merrifield that the staff should continue to work on Issue 15 - Change Authority. The staff is proposing to withdraw that part of the rulemaking because additional time is needed to resolve some recently identified issues. The Change Authority issue has been through the formal rulemaking process - it was included in the proposed rule and has received public comment. To withdraw it at this point is to waste all the time and effort the staff has put into the issue so far. A better option would be for the staff to continue to work on resolving the recently identified issues and developing a solution can be issued as a final rule. I agree with Commissioner Merrifield, that the staff should present a resolution to this issue to the Commission in 6 months.

I also agree with Commissioner Merrifield that the staff should more clearly communicate in the Federal Register the definition of the term "double containment" so public is not misled into thinking it means two separate approved packages.

Finally, I continue to be concerned that this rulemaking has the potential to impact industries that are currently not regulated by NRC, such as the zircon sand and other mineral extraction industries. In my vote on SECY-01-0035, I strongly encouraged the staff to identify and solicit input from industries that possess, use, or transport materials currently exempt from regulatory control to ensure that the potential impacts from this rulemaking are clearly identified and considered in any future regulatory decisions. I see from the summary of comments that the staff did received comments from some of these industries including the zircon sand industry. I also understand that the staff adopted the 10 times exemption multiple value for NORM and other ores that are not part of the fuel cycle to help alleviate this issue. However, I still believe that these rule changes could have a substantial impact on these industries and I continue to encourage that staff to work with them during the implementation of this rule.



Comment. One commenter stated that all radioactive shipments should be regulated and labeled so that transportation workers and emergency responders are aware of the risk.

Response. The comments are acknowledged. DOT regulations include requirements for labels, markings, and placarding packages and conveyances of radioactive materials, and training of Hazmat workers. Existing and proposed regulations for the transportation of radioactive materials consider the potential risk to workers and emergency responders of exposure to these materials. The NRC believes the thresholds for regulation of the transportation of radioactive materials are suitably protective of workers and emergency responders.

Comment. One commenter pointed out that due to the increase in the number of nuclear shipments, the NRC and DOT must strengthen their standards to protect the millions of people, thousands of schools, and hundreds of hospitals residing directly along transportation routes.

Response. The NRC routinely reevaluates the effectiveness of its regulations to ensure that it is meeting its mission to protect the public health and safety. In regulating safe and secure transport of spent nuclear fuel, the NRC has conducted risk studies to consider the fact that a large number of shipments might be made to a future geological repository using current generation cask designs. These studies have confirmed that the current NRC regulations support safe shipments in large numbers to a centrally located storage facility.

Comment. On behalf of the nuclear industry, one commenter said that harmonization is logical in terms of cost and safety. Harmonized rules and uniform standards and criteria allow members of the nuclear industry to know how safe a package is, regardless of where it comes from. Because many other nations have already adopted many of these proposed rules, U.S.

are robust + protective of the public during transportation of spent fuel. Therefore even with an increase in the # of shipments, these shipments can be made safely.

minimum because regulatory differences can lead to confusion and errors and result in unsafe conditions or events. U.S. failure to comply with international safety regulations could easily result in disruption of U.S. participation in international radioactive material commerce, with no commensurate justifiable safety benefit, because other IAEA Member States are under no obligation to accept shipments that do not comply with international regulations.

Comment. One commenter wanted to know how the IAEA drafted its regulations and statistics. The commenter questioned who the IAEA is and why NRC should accept its statistics. The commenter also asked how much input the American public has had on these regulations and noted that Congress and the public have previously rejected IAEA regulations.

Response. The comments concerning the IAEA standards development process and U.S. citizen input to that process are both beyond the scope of this rulemaking. However, as noted in the public meetings held to obtain comments on the proposed rule, DOT is mandated by law to help formulate international transportation standards, and to ensure that domestic regulations are consistent with international standards to the degree deemed appropriate. The law permits DOT the flexibility to accept or reject certain of the international standards. The NRC/DOT evaluation of the IAEA standards has resulted in the two parallel sets of final rule changes. Rejection of an IAEA standard could be based on technical criteria as well as on public comment on proposed rules. The IAEA has Member States that develop standards as a collegial body, and the U.S. is one of those Member States.

Comment. Several commenters urged NRC to improve its scientific understanding and basis for the proposed rulemaking. Two commenters suggested that NRC complete the comprehensive assessments of TS-R-1 and future IAEA standards, the Package Performance Study (PPS), and ~~real~~ cask tests before proceeding with this rulemaking. A commenter stressed that ICRP does not represent the full range of scientific opinion on radiation and health

full-scale

and ignores concepts such as the bystander effect and synergism of radiation with other environmental contaminants. This commenter also stated that the exposure models used to justify certain exposure scenarios are inadequate.

Response. The NRC acknowledges these comments and notes that NRC participates or monitors the work of major, national and international, scientific organizations in the fields of health physics and radiation protection. As such, NRC has access to the latest scientific advances. Moreover, the NRC has completed an assessment of TS-R-1 as part of the development of this rule. The PPS is a research project independent of this rulemaking. Also, see the following comment regarding the ICRP.

Comment. Several commenters stated that the IAEA rulemaking process is not democratic, and their documents are not publicly available and were developed without public knowledge or input. One commenter suggested that the public should have had an opportunity to "comment on or otherwise participate in the earlier formation of the IAEA rules." Another commenter proposed that the NRC act as an intermediary between public opinion and IAEA by improving communications with the public and regulated bodies, providing advanced notice of rulemakings, and receiving comments on proposed rules.

Response. The NRC acknowledges the comments about the IAEA rulemaking process, the ICRP representation of scientific opinion, and the observation on NRC's role as intermediary between the American public and the IAEA, but each of these comments brings up issues that are beyond the scope of the proposed rulemaking. Therefore, no NRC action is necessary. The NRC notes that the IAEA has begun to discuss ways to foster public participation in its standards development process.

Comment. Several commenters stated that IAEA and ICRP regulations should not dictate domestic U.S.-based regulations. Two commenters stated that IAEA does not

Changes were made to this rulemaking.

shipments; the average number of packages per shipment; and the detailed information on curie counts by shipment categories. One commenter believes that the EA should include transportation scenarios, updated data rather than 1982 data, and a quantitative analysis along with a qualitative analysis.

The NRC was criticized for a portion of the EA (page 43), which first identifies information necessary to make a risk-informed decision on the proposed regulation and then discusses the lack of information in the EA. The commenters noted a discrepancy in NRC's efforts, particularly the number of NRC staff and resources devoted to this rulemaking for the past 2 years versus the lack of resources devoted to updating the 1982 data. They stated that the costs associated with the Type C package changes were not included in the EA and that process irradiators are shipping sources equaling about 50 million curies, much greater than the curie count listed in the proposed rulemaking.

Response. The draft EA and RA were developed based on the best information available to the NRC at the time. As part of the rulemaking process, NRC solicited additional information on the costs and benefits of the proposed positions. The information that was made available has been considered in NRC's final decision. The majority of the proposed changes are such that the specific dose information and calculations are not required to determine the appropriateness of adopting or not adopting the change being considered.

Did not address the comment.

Comment. One commenter expressed concerns about NRC's findings of "no significant impact" on radionuclide-specific activity values for a number of issues. The commenter requested that more detailed information be provided "on how many and which radionuclide levels will rise or fall" as a result of proposed changes. The commenter also asked the NRC to define its use of "significantly" and to explain how it determined the level of "risk."

Comment. Several commenters were concerned that the proposed regulations may increase vulnerability to terrorist threats using radioactive materials. A commenter believes that labeling radioactive materials could aid terrorists by identifying the packages as radioactive, while another commenter stated that shipments with or without labels provided potential terrorists with the materials for a dirty bomb. Another commenter requested that NRC put protective measures into place at ports and to guard all nuclear shipments with U.S. military forces. One commenter stated that nuclear shipments should be transported at off-peak hours while all side roads, tunnels, bridges, overpasses, railroad crossings, access to exit ramps, etc., should be secured before the transport vehicle arrives, and that NRC should create a "vehicle-free" buffer zone ahead and behind the shipment. This same commenter advocated FBI background checks on all transporters, drivers, and crew workers involved with nuclear transport. - Two commenters asserted that all new rules should be mindful to the threat of terrorism, which would be superior to considering terrorism in separate rules.

Response. The NRC acknowledges these comments and notes that NRC has taken immediate regulatory actions to address the potential for terrorist activities; these include issuing orders and advisories to its spent fuel licensees prior to initiating rulemaking which takes a longer time, and initiating shipment vulnerability studies. Also, the NRC will make the necessary rule changes.

*should add
statement @
DOT rules reg
Driver background
+ ID cards.*

X

Adequacy of NRC Regulations and Rulemaking Process.

Comment. Three commenters believe that the NRC should better account for low-level radiation. One commenter stated that NRC should use the latest medical knowledge from independent sources (i.e., not IAEA or ICRP data) regarding the medical effects of radiation. Another commenter stated that low-level radiation could cause cell death, cancer, genetic

radiation exposure in the U.S. from natural sources is 3.0 mSv (300 mrem) per year. Although radiation may cause cancers at high doses and high dose rates, there is no current data that unequivocally establishes the occurrence of cancer following exposure to low doses and dose rates -- below about 100 mSv (10,000 mrem). People living in areas having high levels of background radiation -- above 10 mSv (1,000 mrem) per year, such as Denver, Colorado, have shown no adverse biological effects.

The NRC actively and continually monitors research programs and reports concerning the health effects of ionizing radiation exposure. NRC staff monitors the Low Dose and Low Dose Rate Research Program sponsored by the Department of Energy (DOE). The research project is designed to better understand the biological responses of molecules, cells, tissues, organs, and organisms to low doses of radiation. NRC also is co-funding a review of the Biological Effects of Ionizing Radiation (BEIR) by the National Research Council. The BEIR committee will also review and evaluate molecular, cellular, and animal exposure data and human epidemiologic studies to evaluate the health risks related to exposure to low-level ionizing radiation. Both groups provide a comprehensive evaluation of the health risks associated with radiation exposure.

Finally, existing regulatory guidance suggests that protection of individuals (humans) is also protective of the environment. IAEA Technical Report Series No. 332 (Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards) suggests that, in most cases, the environment is being protected by protecting humans. Other empirical evidence suggests that the current system of radiological protection does not harm the environment, even in areas of gross contamination surrounding accident sites such as Chernobyl.

Not clear what the staff is trying to say.

There is "harm" - what measurement system is the staff using?

What is this?

☆ unclear
Need
to revise!

Although many occupational and public areas occupied by individuals may contain materials that result in both radiation and chemical exposure, the NRC has no regulatory authority over any of the materials present including chemicals other than source, byproduct, or special nuclear material, to include chemicals. In many situations, exposures to chemicals and non-NRC regulated materials are under the purview of the U.S. Environmental Protection Agency (EPA).

Comment. Seven commenters opposed the proposed rule because of increased exposure, danger to public health, and increased public health risk.

Response. The NRC disagrees that the proposed rulemaking will result in any undue increase in exposure, endangerment to public health, or increase in health risk. See earlier comment responses for further details.

Comment. One commenter stated that U.S. agencies have not adequately represented public opinion regarding transportation safety. The commenter was concerned that the number of irradiated fuel and plutonium shipments in the nation will increase as the proposed regulations weaken container safety standards.

Response. The DOT and NRC represent the United States before the IAEA, DOT as the U.S. Competent Authority supported by the NRC. Both agencies have information and are aware of public opinion regarding transportation safety in the United States. The NRC disagrees with the comment that U.S. agencies have not adequately represented public opinion. Additionally, NRC prepares its rules in compliance with Administrative Procedure Act (APA) requirements. The APA requires that public comments be requested, considered, and addressed before a final rule is adopted unless there are exigent reasons to bypass the public comment process.

AFFIRMATION ITEM

RESPONSE SHEET

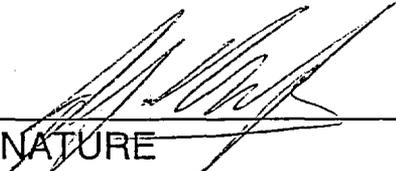
TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Merrifield
SUBJECT: **SECY-03-0141 - FINAL RULE TO REVISE 10 CFR
PART 71 TO BE COMPATIBLE WITH IAEA
TRANSPORTATION SAFETY STANDARDS [TS-R-1]
AND MAKE OTHER NRC-INITIATED CHANGES**

Approved */in part* Disapproved */in part* Abstain _____

Not Participating _____

COMMENTS:

See attached comments.



SIGNATURE

10/30/03

DATE

Entered on "STARS" Yes No _____

Comments from Commissioner Merrifield on SECY-03-0141:

I approve, as revised in the following comments, the staff recommendations in SECY-03-0141 concerning a final rule on transportation requirements. This was a complex, controversial rulemaking effort and I want to commend the staff for their efforts. Areas requiring revision and/or further effort by the staff are as follows:

1. Issue 2 - Radionuclide Exemption Values

This rulemaking creates an inconsistency that should be corrected concerning the shipment of natural ores. The rulemaking allows transportation exemptions of up to ten times the exempt values in the rule for shipments of ore or NORM intended for mineral production or disposal. However, it would not exempt shipments of ore or NORM intended for isotope processing that is part of the nuclear fuel cycle. There is insufficient time to resolve this singular issue and maintain the current schedule with DOT for processing the entire rulemaking package. However, in a separate action, I believe the staff should pursue removing this apparent double standard with DOT and allow a similar exemption for material with equivalent risk. In order to be consistent with our overall risk-informed approach to regulations, staff should advocate change proposals in future revisions of the IAEA transportation regulations that would treat materials consistently regardless of their intended use.

2. Issue 8 - Grandfathering

I recognize that for international shipments the use of transportation packages approved under the 1967 design criteria will no longer be allowed. However, the staff has not made a safety case for why the 1967 design criteria is inadequate for domestic shipping. The principal staff argument appears to be that for policy reasons our domestic shipping requirements should be compatible to international requirements in this area. There is no requirement for a backfit analysis to justify changing requirements in this area. The reality is that although the staff is aware of the number of approved 1967 designs that exist, the staff has very little knowledge of the actual number of transportation containers of each design. Therefore the staff has an insufficient understanding of the potential financial impact on individual businesses of phasing out the 1967 designs. From the information provided to me by the staff, one or more licensees that meet the Small Business Administration (SBA) definition of small businesses may be adversely and disproportionately affected by this change. Therefore, with very little understanding of the actual consequences of this change on these disproportionately affected small businesses, the staff is nonetheless suggesting a change in our requirements, despite sparse safety justification. Such an action is clearly inconsistent with the NRC Principles of Good Regulation.

The staff should reevaluate the impact of this proposal on small businesses, engage with DOT again on the justification for phasing out the 1967 designs for domestic use, and then come back to the Commission with another recommendation. I recognize that this may cause a delay in issuing the total rulemaking package. As an alternative, staff could negotiate with DOT that the final rule would state that the 1967 designs are adequate for domestic shipping and both rulemakings (DOT's and NRC's) could proceed on schedule.

3. Issue 15 - Change Authority

This issue is a NRC initiative that is not related to compatibility with IAEA standards. It relates to allowing holders of transportation certificates for dual use canisters (i.e., canisters which can be used for transportation and storage) to make limited changes without NRC approval. The Commission had proposed this regulatory change and noticed the rulemaking for public comment. After receiving comments from stakeholders (with basically the industry supporting the proposal and some public interest groups opposed to the proposal), the staff is proposing to withdraw the rulemaking because of some recently identified technical issues that should be resolved. However, these technical issues have just recently been identified by the staff and have not been externally communicated to or discussed with the stakeholders. The staff believes they need to withdraw this proposal because of inadequate time to address these issues before finalizing this specific rulemaking package. However, our stakeholders have been provided no specific justification for this recent staff proposal and it appears as if the Commission is rejecting the proposal, which is not true from my perspective. Changing regulatory positions at the last minute is an example of poor regulatory predictability. This rulemaking issue has been publically noticed for a considerable period of time, and this last minute identification of new technical issues in a rulemaking package with time constraints is an example of poor communication with external stakeholders. I am willing to let this much larger rulemaking package proceed. However, I do not agree that this specific rulemaking effort should start over. Staff will need to work with OGC on the specific wording of the Federal Register Notice, but it should indicate that staff will work with appropriate stake holders to resolve new concerns recently identified by the staff and propose a final regulatory solution to the Commission. That solution, which could be a final rule, should come to the Commission in six months after the date of the SRM on this SECY paper.

4. Issue 17 - Double Containment

I approve the staff recommendation to eliminate certain existing requirements for double containment of shipments of plutonium. The staff has provided an adequate safety justification for their proposal. However, this is an example of poor communication which can raise false expectations by the public concerning our regulatory requirements. Use of the term "double containment" can easily give to the public the false impression that the transportation package consists of two containers (one inside the other) and each container is fully qualified per the NRC requirements. Under this false impression, removing the requirement for a second container would obviously result in a significant reduction in the level of protection (even though the new level of protection may be declared by the NRC to be adequate). However, this is totally a false impression, particularly for the TRUPACT II design, which was the major design of concern in public comments. For the TRUPACT II design, the term "double containment" means that at the areas where leakage is expected (i.e. the joint between the upper lid and the base) there are two seals to prevent leakage. It is not one approved container inside another approved container; and thus, removing the requirement for the second seal is of minimal safety significance. This is not clear from reading the Federal Register Notice and staff should more clearly communicate what the term "double containment" means in the context of this regulation.



10/30/03