

RULEMAKING ISSUE (Affirmation)

August 15, 2003

SECY-03-0141

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: 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

PURPOSE:

To request Commission approval for publication of a final rule that will amend 10 CFR Part 71.

SUMMARY:

This paper presents the 10 CFR part 71 final rule to the Commission for its consideration. In a Staff Requirements Memorandum (SRM) dated July 10, 2001, the Commission approved publication of the Part 71 proposed rule. The proposed rule was published in the Federal Register on April 30, 2002, for a 90-day public comment period (67 FR 21390). The Department of Transportation (DOT) parallel rule was published on the same date. The staff held two public meetings during the public comment period for the proposed rule. The first meeting was held in Chicago, Illinois, on June 4, 2002, and the second meeting was held at the TWFN Auditorium, NRC Headquarters, on June 24, 2002. A total of 190 comments were received. Based on its analysis of the public comments, the staff affirms its proposed recommendations for all the issues except for issue 15 (Change Authority). The staff is recommending that NRC not proceed with the proposed change authority in the final rule. Additionally, the comments prompted minor changes to the proposed rule language regarding Issues 5 (Criticality Safety Index), 9 (Definitions), and 16 (Fissile Material Exemptions). A regulatory analysis and an environmental assessment have been completed to support this rule. The rule is being coordinated with the DOT. Also provided for Commission approval is a notice that will revise the Enforcement Policy to make it consistent with the rule.

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BACKGROUND:

In an SRM dated September 17, 1999 (SECY-99-200, Attachment 1), the Commission directed the staff to prepare a rulemaking plan that addressed the need to make 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," compatible with the latest revision of the International Atomic Energy Agency (IAEA) transportation safety standards. The IAEA revises its transportation standards periodically, with the last edition published in December 1996. This edition was amended in June 2000 and issued as No. TS-R-1. The Commission also directed the staff to address, as part of the overall rulemaking, the remaining issues from the 1997 emergency 10 CFR Part 71 final rule entitled, "Fissile Material Shipments and Exemptions" (62 FR 5907; February 10, 1997).

On November 9, 1999, the Commission held a public meeting on nuclear materials and waste activities with invited stakeholders. As a result of that meeting, the Commission directed the staff, in a letter dated December 13, 1999 (Attachment 2), to improve stakeholder public participation in the Nuclear Regulatory Commission's (NRC) activities, including rulemaking. The staff subsequently provided the Commission with an issues paper (SECY-00-0117) that presented a summary of the changes being considered in the Part 71 rulemaking, and requested approval to solicit early public input on these changes. In an SRM dated June 28, 2000 (SRM-00-0117, Attachment 3), the Commission directed the staff to publish the Part 71 issues paper for public comment (65 FR 44360; July 17, 2000), and also approved the enhanced public-participation process.

Subsequently, three public meetings were held: a roundtable workshop on August 10, 2000, at the NRC Headquarters, and two townhall style meetings on September 20, 2000, in Atlanta, GA, and September 26, 2000, in Oakland, CA. Participation in these meetings was broad, and included members of: the public; environmental and public interest groups; State government representatives; the Western Governor's Association; the U.S. Department of Energy; the DOT; the Nuclear Energy Institute; the radioactive material shipping industry; the oil and gas industry; and the mineral industry. Transcripts of the meetings, as well as a summary of the comments, were provided to the Commission, and were also placed on the NRC rulemaking interactive website at <http://ruleforum.llnl.gov/>. The public comment period on the issues paper closed on September 30, 2000. A total of 48 written comments were received. Working from the issues paper and the received comments, the staff developed a proposed rule.

In an SRM dated July 10, 2001, the Commission directed the staff to publish the Part 71 proposed rule in the Federal Register, and to continue the enhanced public participation process (SECY-01-0035; Attachment 4). In addition, the Commission directed the staff to add a section to the proposed rule to clearly solicit public comments and obtain information on the costs and benefits of the proposed requirements of the rule. The proposed rule was published in the Federal Register on April 30, 2002, for a 90-day public comment period (67 FR 21390). The staff held two public meetings during the public comment period for the proposed rule. The first meeting was held in Chicago, Illinois, on June 4, 2002, and the second meeting was held at the TWFN Auditorium, NRC Headquarters, on June 24, 2002.

DOT, as the lead agency for the regulation of transportation of hazardous material in the United States, has responsibility as a co-regulator with NRC for transportation of radioactive materials. DOT also serves as the U.S. Competent Authority before the IAEA and foreign countries on

transport issues. The Part 71 final rule has been coordinated with DOT to ensure that consistent regulatory standards are maintained between NRC's Part 71 and DOT's Hazardous Materials Regulations (in particular, 49 CFR Parts 171-178), and to ensure that both rules have the same effective dates, and are published on approximately the same schedule. The NRC staff coordinated the NRC proposed rule with DOT, and the two rules were published in the Federal Register on April 30, 2002, for a 90-day public comment period.

DISCUSSION:

The staff received 190 public comment letters, in addition to numerous comments received at the public meetings (the meeting were recorded and the transcripts were placed on the NRC website). All of these comments are summarized in the public comment summary document (Attachment 5) and organized under the following 19 issues:

- A. TS-R-1 Compatibility Issues
 - Issue 1: Changing Part 71 to the International System of Units (SI) Only
 - Issue 2: Radionuclide Exemption Values
 - Issue 3: Revision of A_1 and A_2
 - Issue 4: Uranium Hexafluoride Package Requirements
 - Issue 5: Introduction of the Criticality Safety Index Requirements
 - Issue 6: Type C Package and Low Dispersible Material
 - Issue 7: Deep Immersion Test
 - Issue 8: Grandfathering Previously Approved Packages
 - Issue 9: Changes to Various Definitions
 - Issue 10: Crush Test for Fissile Material Package Design
 - Issue 11: Fissile Material Package Design for Transport by Aircraft
- B. NRC-Initiated Issues
 - Issue 12: Special Package Approvals
 - Issue 13: Expansion of Part 71 Quality Assurance Requirements to Holders of, and Applicants for, a Certificate of Compliance
 - Issue 14: Adoption of American Society of Mechanical Engineers (ASME) Code
 - Issue 15: Change Authority for Part 71 Certificate Holders
 - Issue 16: Fissile Material Exemptions and General License Provisions
 - Issue 17: Double Containment of Plutonium (PRM-71-12)
 - Issue 18: Contamination Limits as Applied to Spent Fuel and High-Level Waste (HLW) Packages
 - Issue 19: Modifications of Event-Reporting Requirements

General comments were collected in a separate category and are located in Section II of the Federal Register Notice (FRN) (Attachment 6). The themes in these general comments included terrorism concerns, States rights, and NRC and DOT coordination.

Based on its analysis of the public comments, the staff affirms its recommendation that NRC adopt the TS-R-1 position on issues 2, 3, 4, 5, 7, 8, 9, 10, and 11 in the final rule. The staff also affirms its proposed recommendation that NRC not adopt the TS-R-1 position on issues 1 and 6. Additionally, there were changes made in the proposed rule language regarding issues 5 and 9 as a result of public comments.

On the NRC-initiated issues, the staff affirms the proposed requirements on issues 12, 13, 17, and 19. The staff also affirms its previous recommendation on issue 14 and issue 18. The staff has re-examined its proposed limited change authority [issue 15] for the dual-purpose package and is now recommending that further analysis be done to more accurately assess the impact of the change authority, and that NRC not proceed with this issue in the final rule. Also, as a result of public comments, changes were made in the proposed language of issue 16 (fissile material exemptions).

The staff's recommendations are discussed in detail in the attached FRN. The DOT staff's recommended final rule is consistent with these recommendations.

The staff notes that four issues generated a high level of interest and discussion in public and staff meetings and comments received on the NRC website. These issues are summarized below.

1. *Issue 2. "Radionuclide Exemption Values."* Consistent with the proposed rule and DOT's rule, the staff is recommending adoption of the IAEA radionuclide-specific Table of Exempt Concentration Values instead of using the current single-value activity of 70 Becquerels per gram limit for all radionuclides. The staff also recommends adoption of the IAEA provision that allows 10 times the specified exemption values for transport of naturally occurring radioactive material (NORM) and ores if these ores/materials are not intended to be processed for use of their isotopes.

Exemption values in terms of activity concentrations and total activity were initially derived for inclusion in IAEA Safety Series No. 115, known as the Basic Safety Standard (BSS) on the basis of (a) an individual effective dose of 10 mSv in a year for normal conditions, or (b) a collective dose of 1 person-Sv in a year of practice for normal conditions. The exemption values were derived by using a variety of exposure scenarios and pathways that did not explicitly address the transport of radioactive material. Additional calculations were performed for transport specific scenarios during TS-R-1 development, that were then compared with the values in the BSS. Ultimately, an equivalent set of exemption values based on the BSS were adopted, given that the use of different exemption values in various practices may give rise to problems at interfaces and may cause legal and procedural complications. The exemption values in TS-R-1 are consistent with those found in the IAEA's Basic Safety Series. There is ongoing work to coordinate the efforts on draft guidance, DS-161, Radioactivity in Material not Requiring Regulation for Purposes of Radiation Protection, that is intended to refine the applicability of regulatory control through exclusion and clearance principles. In general, the values listed in DS-161 are equal to or lower than the exemption values specified in TS-R-1.

In SRM-SECY-01-0035, the Commission recognized that the proposed recommendation resulted in different exemption levels being proposed for materials that pose equivalent risks (i.e., ore or NORM shipments intended for mineral processing or disposal, versus the same or similar ore/NORM shipments intended for isotope processing that is part of the nuclear fuel cycle). Therefore, the staff was directed to pursue this issue further during the rulemaking process. The staff has discussed this issue with the public and affected industries (mining/mineral, and oil and gas industries). After consulting the DOT and considering the costs of regulation to those industries, which are currently exempt from DOT regulations, the staff concluded that adoption of the 10 times provision is recommended. Not providing this exemption would result in extending transportation regulations to many shipments of ores and natural materials containing NORM with very low activity levels. This would add a large regulatory burden with little associated safety benefit. Therefore, this provision has been adopted by the DOT (per a Memorandum of Understanding with DOT, the definition of what constitutes a radioactive material during transport is the responsibility of DOT).

The Commission may wish to alternatively consider the option of extending the 10 times provision to all natural material containing NORM and ore shipments regardless of intended use following processing. This option would remove an apparent double-standard related to the intent of use of the material, but would preserve the IAEA dose-based model/methodology. However, if adopted by the Commission, this option will need to be examined and discussed with the DOT to ensure their agreement and determine the impact, and could result in a delay in the publication of the NRC and DOT final rules. In future revision cycles of the IAEA transportation regulations, the staff would propose to advocate change proposals that would treat materials consistently regardless of their intent of use, consistent with risk-informed approaches.

2. *Issue 8. "Grandfathering Previously Approved Packages."* The staff affirms the proposed amendments to discontinue authorization to use packages approved under the provisions of the 1967 edition of the IAEA Safety Series No. 6, and to allow a 4-year transition period from the effective date of the final rule. As a result of discussions with the DOT, this transition period was changed from 3 years in the proposed rule to 4 years in the final rule. With the final rule effective date being one year, the transition period is effectively 5 years. Other amendments include the following: packages approved under NRC standards compatible with the provisions of the 1973 or 1973 (as amended) editions of IAEA Safety Series No. 6 no longer may be fabricated, but may still be used; packages approved under NRC standards that are compatible with the provisions of the 1985 or 1985 (as amended 1990) editions of IAEA Safety Series No. 6, and designated as "-85" in the package identification number, may not be fabricated after December 31, 2006, but may continue to be used; and package designs approved under any pre-1996 IAEA standards may be resubmitted to the NRC for review against the current standards in 10 CFR Part 71. These changes will allow industry to phase out old packages and phase in new ones, and they bring the U.S. transportation regulations into alignment with those in place internationally.

The grandfathering issue generated some industry interest from a small number of package users who focused on the potential number of previously approved packages that could not be fabricated or used in the future. Their concern focused on negative

business impacts, elimination of packages that have not had performance problems, requirements to develop and test new package designs (or prove old designs remain viable) , and potentially creating orphan sources. The commenters' argument against phase out of approved designs was that there is no safety justification for discontinuing their use. The staff determined that these older designs did not have safety enhancements of packages approved to later standards, and that, in many cases, the safety basis for the package design approval was not well established. The lack of quality assurance records for many of these older packages makes verification of durability and their design basis difficult. Further, it is desirable to have packages in use that meet the requirements that have been adopted in later versions of IAEA standards and U.S. regulations. The staff notes, however, that transportation packages approved to the 1967 version of the regulations have compiled a long record of safe use. The staff's recommendation, to phase out the domestic use of 1967 package designs, is partly based on technical questions and partly on policy to be consistent with DOT and world wide practice.

3. *Issue 15. "Change Authority for Part 71 Certificate Holders."* The staff proposed extension of change authority to Part 71 certificate holders, to allow them to safely make limited changes to the design of a transportation package — just as reactor and spent fuel storage facilities can safely make changes to their facilities (under 10 CFR 50.59 and 72.48). This change authority was proposed only for domestic dual-purpose spent fuel storage and transportation packages [Type B(DP)], i.e., for systems approved for both the transportation and storage of spent fuel. However, the staff has re-evaluated the proposed requirements and concluded that the proposed change process should not continue in the final rule because these added requirements would result in new and significant regulatory burdens and costs that were beyond those considered in the proposed rulemaking. Moreover, the staff recognizes the concerns of the general public related to the allowance of changes in the design of a B(DP) package without prior NRC approval. Considering both industry interest in the advantages of a design change process not requiring prior NRC approval and the benefits that have been realized by a similar change made in Part 72, the staff proposes to pursue further, more detailed analysis of this issue for consideration in a future rulemaking. In addition, the existing mechanisms for approval and amendment for package designs under Part 71 allows certificate holders to make limited design changes that are not safety significant without NRC approval.
4. *Issue 17. "Double Containment of Plutonium (PRM-71-12)."* This issue results from a petition for rulemaking (PRM-71-12) that requested elimination of the double-containment requirements for plutonium shipments. There is no comparable IAEA requirement for double containment of plutonium. The staff recommends granting this petition, in part, by eliminating the double-containment requirements for plutonium, because the current, single-containment-barrier, Type B package standards, which are used for transportation of spent fuel, would provide adequate accident protection when applied to packages transporting plutonium. However, the staff recommends retention of the requirement that shipments whose contents contain greater than 0.74 TeraBecquerels (20 Curies) of plutonium must be made with the contents in solid form.

The staff's recommendation is supported by the robust design characteristics of Type B packages and consistently treats the health risks from all nuclides using the A_1/A_2 system. However, the reasons originally envisioned for the double-containment requirement (i.e., many liquid plutonium shipments for reprocessing) never materialized, and that the double-containment requirement was neither risk-informed nor performance-based. The staff notes that there were many public comments against the elimination of the double-containment requirement, with the most prominent a letter from the Western Governors Association signed by six governors opposing this change to the regulation citing both safety and security concerns. The letter also indicated awareness of a high level of State interest and strong views on this issue.

Additionally, as a result of this rulemaking, there is a need to revise Part X of the Enforcement Policy, "Enforcement Action Against Non-Licensees," to make clear that non-licensees who are subject to specific regulatory requirements, e.g., Part 71, will be subject to enforcement action, including Notices of Violation and Orders.

COORDINATION:

The draft FRN was provided to the Agreement States for comment on June 3, 2003. The Agreement States' comments covered a number of issues, including requesting exemptions for laboratory samples, and revisions to the Agreement Compatibility table. The staff was able to respond to most of the issues raised by the Agreement States.

The Office of the General Counsel has reviewed this final rule and has no legal objection. The Office of the Chief Financial Officer has reviewed the Commission paper for resource impacts and has no objections. This paper has been coordinated with the Office of Enforcement.

RECOMMENDATION:

That the Commission:

1. Approve for publication in the Federal Register the final amendments to Part 71.
2. Approve for publication in the Federal Register the revision to the Enforcement Policy (Attachment 11).
3. Note:
 - a. That the final rule will be published concurrent with the companion final rule from the U.S. Department of Transportation.
 - b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
 - c. That a final Regulatory Analysis has been prepared for this rulemaking (Attachment 7).

- d. That a final Environmental Assessment has been prepared for this rulemaking (Attachment 8).
- 5. The staff has determined that this action is not a “major rule,” as defined in the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1995 [5 U.S.C (804(2))] and has confirmed this determination with the OMB. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 9).
- f. The appropriate Congressional Committees will be informed of this action.
- g. That a press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register.
- h. That the clearance already received from OMB on the proposed rule information collection requirements will be revised based on the changes made in the final rule and will be forwarded to OMB no later than the date the final rule is submitted to the Office of the Federal Register for publication.
- i. That draft guidance documents (Reg Guide 7.9, Standard Format and Content of Part 71 Applications for Approval of Packaging of Type B, Large Quantity, and Fissile Radioactive Material (01/80), and Reg Guide 7.10, Establishing Quality Assurance Programs for Transport of Radioactive Material (06/86)) are being developed and are anticipated to be available for publication by the time the final rule is published in the Federal Register.
- j. That a letter will be sent to the petitioner in PRM-71-12 to inform them of NRC decision (Attachment 10).

- k. That the resources to complete and implement this rulemaking are included in the current budget.

/RA/

William D. Travers
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Attachments:

1. SRM-SECY-99-200
2. SRM-M991109A
3. SRM-SECY-00-0117
4. SRM-01-0035
5. Summary and Categorization of Public Comments
6. Final Rule FRN
7. Regulatory Analysis
8. Environmental Assessment
9. SBREFA forms
10. Letter to Petitioner (PRM-71-12)
11. Enforcement Policy Revision FRN

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/RA/

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1. SRM-SECY-99-200
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NMSS Ticket No. 200300058 ML

File Name: (O:\NMSS\TANIOUS\Part 71 Rule\Part 71-final-SECY-Paper-7-29-03.wpd)*See previous concurrence

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