

RULEMAKING ISSUE NOTATION VOTE

March 2, 2001

SECY-01-0035

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED RULE FOR REVISING 10 CFR PART 71 FOR COMPATIBILITY WITH IAEA TRANSPORTATION SAFETY STANDARDS [TS-R-1], AND FOR MAKING OTHER NRC-INITIATED CHANGES

PURPOSE:

To request Commission approval to: (1) publish a proposed rule, in the Federal Register (FR), that would amend 10 CFR Part 71; and (2) continue using an enhanced public-participation process (website and public meetings), during the proposed rule public comment period, to solicit maximum public input.

BACKGROUND:

The Commission directed the staff, in a Staff Requirements Memorandum (SRM), dated September 17, 1999 [SRM-SECY-99-200 (Attachment 1) - "Federal Register Notice Responding to Public Comments Received on an Emergency Final Rule for Fissile Material Shipments"], to prepare an overall rulemaking plan that addresses the need to make Part 71, "Packaging and Transportation of Radioactive Material," compatible with ST-1, the latest revision of the International Atomic Energy Agency (IAEA) transportation safety standards. The IAEA has been revising its transportation standards on approximately a 10-year cycle, with the last edition, ST-1, published in December 1996. This edition was revised in June 2000 and

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published as No. TS-R-1. The revisions in TS-R-1 were basically an errata redesignating ST-1 as TS-R-1. The Commission also directed the staff to address, as part of the overall rulemaking plan, the unintended economic impact of its emergency Part 71 final rule entitled, "Fissile Material Shipments and Exemptions," (62 FR 5907; February 10, 1997).

On December 13, 1999, the Commission directed (M991109A, Attachment 2) the staff, after the Commission's meeting on nuclear materials and waste activities with invited stakeholders, to improve stakeholder public participation in the Nuclear Regulatory Commission's (NRC) activities, including rulemaking.

In SECY-00-0117, "Rulemaking Process for Revising 10 CFR Part 71 for Compatibility with IAEA Transportation Safety Standards (ST-1), and to Make Other Changes", dated May 30, 2000, the staff provided the Commission an issues paper that presented a summary of the changes being considered in the Part 71 rulemaking to solicit early public input on these changes. In SRM-00-0117 dated June 28, 2000 (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 meetings on September 20, 2000, in Atlanta, GA, and September 26, 2000, in Oakland, CA. Public participation in these meetings was broad, and included members of the public, environmental and public interest groups, state representatives, the Western Governor's Association, the U.S. Department of Energy, the U.S. Department of Transportation (DOT), the Nuclear Energy Institute, representatives of 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. In addition, an NRC web page similar to that prepared for the control of solid materials was created at: <http://www.nrc.gov/NMSS/IMNS/transport.html>.

DOT is the lead agency for the regulation of transportation of hazardous material in the United States, and is a co-regulator with NRC of transportation of radioactive material. DOT is also the U.S. competent authority for interaction with the IAEA. Therefore, this revision to Part 71 is being 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 are published on approximately the same schedule. DOT's proposed regulations are intended to be consistent with NRC's proposed regulations. DOT published for public comment an Advance Notice of Proposed Rulemaking containing the ST-1 changes on December 28, 1999 (64 FR 72633). During the public meetings, a DOT representative made a presentation at the meetings and joined the NRC staff in responding to public comments as they relate to the DOT rulemaking. DOT committed to review public comments for applicability to their proposed changes.

DISCUSSION:

The NRC staff formed a working group (WG) that included staff from the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of States and Tribal Programs (STP), the Office of the General Counsel (OGC), as well as a representative from DOT. Further, a steering group consisting of NMSS and OGC managers provided direction in the development of the proposed rule. Also, as directed by SRM M000211, dated March 9, 2000 (Attachment

4), the staff prepared a comparison between TS-R-1 and Part 71 (Attachment 5), to determine the major differences between these two regulations.

The issues paper presented 18 issues for comment. As directed by the Commission in SRM-SECY-00-0117, issue 18 was added prior to publication in the Federal Register, to discuss the current IAEA standards for package surface removable contamination. Subsequent to the publication of the issues paper, the staff has added issue 19: Event Reporting Requirements. The addition of this issue was an outgrowth of staff review of reporting requirements to be consistent with changes to other reporting requirements (SECY-00-0093, Rulemaking to Modify the Event Reporting in 10 CFR 50.72 and 50.73 and for Independent Spent Fuel Storage Installations (ISFSI) in 10 CFR 72.216).

In developing the staff positions on the 19 issues in this proposed rule, the staff considered the existing Commission policy statements (e.g., NRC's metrication policy); the NRC's previous positions on some of these issues (e.g., on the IAEA radionuclide exemption values, the Type C package, and uranium hexafluoride packaging requirements); technical considerations from the NRC staff's latest experience with the 19 issues, either in the United States, or from the latest staff interactions at the IAEA meetings in Vienna; and, finally, the public comments received in the meetings, by mail, and on the NRC web site. The attached draft Federal Register Notice (FRN) (Attachment 6), contains the Part 71 proposed rule with an analysis and proposed staff position for each issue. Summary and categorization of public comments is enclosed as Attachment 7. A draft Regulatory Analysis and draft Environmental Assessment are also attached (Attachments 8 and 9, respectively).

The following is the list of Part 71 issues discussed in the FRN:

A. TS-R-1 or ST1 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

On the TS-R-1 compatibility issues the staff is recommending that NRC adopt the TS-R-1 position on issues 2, 3, 4, 5, 7, 8, 9, 10, and 11, either fully or with some modification. The staff is also recommending that NRC not adopt the TS-R-1 position on issues 1 and 6. On the NRC-initiated issues, the staff is recommending adoption of new requirements on issues 12, 13, 15, 16, 17, and 19. The staff is also recommending that NRC not adopt the ASME Code for storage and transportation cask fabrication (issue 14), and not adopt surface contamination-limits for large packages (spent fuel and HLW packages)[issue 18]. These recommendations are discussed in the FRN. DOT is in agreement with these recommendations.

The staff notes that several of the issues in this proposed rule engendered a high level of interest and discussion in public and staff meetings and comments on the NRC website on the issues paper. Further, the comments indicate a wide range of views on the appropriate action to resolve four of these issues. These issues are: issue 2, "Radionuclide Exemption Values," issue 12, "Special Package Approvals," issue 15, "Change Authority for Part 71 Certificate Holders," and issue 17, "Double Containment of Plutonium (PRM-71-12)." These four issues are summarized below. A detailed discussion is contained in the attached FRN (Attachment 6).

1. *Issue 2:* This issue presents the NRC with the challenge of whether to adopt a uniform-dose IAEA standard (and a radionuclide-specific Table of exemption values) versus using the current simpler single-value activity of 70 Bq/g limit for all radionuclides. The IAEA standard contains a provision to allow 10 times the specified exemption values for natural material and ores containing naturally occurring radioisotopes provided those ores/material are not intended to be processed for use of their isotopes. The staff notes that adopting the IAEA exemption provisions to harmonize with the IAEA standards results in an inconsistent level of protection, and a different regulatory treatment of these natural material and ores shipments based on the end use of the shipments, i.e., processing for extraction of radioisotopes versus processing for extraction of minerals, or disposal. However, the staff recommends adoption of the use of radionuclide-specific exemption values.
2. *Issue 12:* This issue is whether the NRC should propose Part 71 amendments to provide a standard for review of large-object packages, such as the Trojan Reactor Vessel, rather than reviewing each request on a case-by-case basis via the current exemption process, each of which requires Commission approval. The staff recommends the establishment of standards for approving these large objects as packages.
3. *Issue 15:* This issue discussed possible authority for certificate holders 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). The staff recommends the extension of change authority to Part 71 certificate holders, but only for domestic dual-purpose spent fuel storage and transportation packages, i.e., for systems approved for both the transportation and storage of spent fuel.
4. *Issue 17:* This issue is whether the current, single-containment-barrier, Type B package standards would provide adequate accident protection when applied to packages transporting plutonium, versus the existing double containment requirements. There is no comparable IAEA requirement for double containment of plutonium. The staff believes that a single Type B containment barrier is adequate for all transportation packages.

The staff plans to conduct a number of facilitated public meetings during the public comment period to discuss the proposed rule to enhance public input. These meetings will be held in locations across the country. The staff will provide the Commission with summaries of each of the public meetings. The proposed rule will be posted on the NRC's website and the staff plan to maintain the website dedicated for Part 71 up to date. The staff notes that, since publication of the Part 71 issues paper in July 2000, it made supporting information and documents available to the public, both on the Part 71 website and in the public document room.

The staff is particularly seeking stakeholders' comments related to quantitative information on the costs and benefits resulting from the proposed requirements, and operational data on exposures that might result (or be reduced) from implementing these proposed requirements. The staff hopes that stakeholder comments will help to quantify the potential impact of these proposed changes and will assist NRC in developing a risk-informed final rule.

The draft FRN was provided to the Agreement States for comment. The Agreement States' input was considered in the development of this draft proposed rule.

In developing its positions on each of the issues, the staff considered the four performance goals in the NRC Strategic Plan. For all issues, the performance goal of maintaining safety, protection of the environment, and the common defense and security, has been met. The remaining three performance goals: increasing public confidence; making the NRC activities and decisions more effective, efficient, and realistic; and reducing unnecessary regulatory burden on stakeholders, were addressed to varying degrees throughout the issues. For example, the staff believes that harmonizing Part 71 with the IAEA International regulations (issues 1 to 11) will both increase regulatory efficiency and effectiveness, and reduce unnecessary regulatory burden on licensees by eliminating the need to satisfy different regulatory requirements depending on whether the package is shipped domestically or internationally. The staff considered comments on the issues paper concerning any reduction in regulatory requirements such as the revised A_1 and A_2 values and addition of a change authority for certificate holders and believes that, on balance, public confidence will be increased because more accurate modeling of the dose will be used and safety will be maintained. In addition, the staff believes that overall public confidence will be increased as a result of this rulemaking because of the addition of regulatory requirements such as the criticality safety index and expansion of quality assurance requirements to certificate holders. The staff will further consider the relationship of this rulemaking and the performance goals in the NRC Strategic Plan as a result of comments on this proposed rule.

SCHEDULE:

Because of the complexity and size of this rulemaking, the staff is recommending a 90-day public comment period (typically 75 days) for the proposed rule during which time the public meetings would be held. The NRC also needs to ensure that the proposed and final rules on amending Part 71 and DOT's companion regulations are published concurrently. Thus, the staff proposes changing the current due date for delivery of a final rule to the Commission from the current date of June 30, 2002, to a date of one year after the close of public comment period. The staff will coordinate with DOT to publish the final rule concurrent with DOT's final rule.

COORDINATION:

OGC has reviewed this proposed 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. The Office of the Chief Information Officer has reviewed the Commission paper for information technology and information management implications and concurs in it. New information requirements resulting from this proposed rule will be submitted to the Office of Management and Budget at the same time the rule is forwarded to the Federal Register for publication. This paper has been coordinated with the Office of Enforcement.

RECOMMENDATION:

That the Commission:

1. Approve for publication in the Federal Register the proposed amendments to Part 71.
2. Note:
 - a. That the proposed amendments will be published in the Federal Register allowing 90 days for public comment.
 - b. That the proposed amendments will be published in a timeframe compatible with the proposed amendments from the U.S. Department of Transportation's associated rulemaking.
 - c. That the staff will use an enhanced public participation process during the public comment period. A separate notice will be published in the Federal Register, subsequent to the publication of the proposed amendments, identifying the dates and locations of the public meetings on this rulemaking.
 - d. 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).
 - e. That a draft Regulatory Analysis has been prepared for this rulemaking (Attachment 7).
 - f. That a draft Environmental Assessment has been prepared for this rulemaking (Attachment 8).
 - g. The appropriate Congressional Committees will be informed of this action.
 - h. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.
 - i. That OMB review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.
 - j. That the resources to complete and implement this rulemaking are included in the current budget.
 - k. That the staff will deliver a final rule to the Commission one year after the close of the public comment period, or concurrent with DOT's final rule.

/RA/

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Attachments:

1. SRM-SECY-99-200
2. SRM-M991109A
3. SRM-SECY-00-0117
4. SRM M000211
5. Comparison Between TS-R-1 and 10 CFR Part 71
6. Proposed Rule FRN
7. Summary and Categorization of public comments
8. Draft Regulatory Analysis
9. Draft Environmental Assessment

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