

**RULEMAKING ISSUE**  
**Notation Vote**

DATE: July 28, 2016 SECY-16-0093

FOR: The Commissioners

FROM: Victor M. McCree  
Executive Director for Operations

SUBJECT: RULEMAKING PLAN FOR REVISIONS TO TRANSPORTATION  
SAFETY REQUIREMENTS AND HARMONIZATION WITH  
INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION  
REQUIREMENTS

PURPOSE:

The purpose of this paper is to request Commission approval to initiate a rulemaking related to harmonizing Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," with the International Atomic Energy Agency (IAEA) and the U.S. Department of Transportation (DOT) regulations. This rulemaking would revise 10 CFR Part 71 to be compatible with the IAEA and DOT regulations and include additional U.S. Nuclear Regulatory Commission (NRC) staff-initiated administrative, editorial, or clarification changes.

SUMMARY:

Historically, rulemaking to harmonize and maintain 10 CFR Part 71 compatibility with the IAEA and DOT regulations was initiated when there were changes in the IAEA or the DOT regulations that required harmonization. The NRC and the DOT have determined that there will be a need for rulemaking to maintain harmonization based on the latest revision of IAEA's "Specific Safety Requirements Number SSR-6" (SSR-6), "Regulations for the Safe Transport of Radioactive Material," 2012 Edition, along with an additional proposed revision to SSR-6 estimated to be published by 2018. The NRC staff would continue to work with DOT to determine the extent of harmonization needed through rulemaking.

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The staff recommends revising 10 CFR Part 71 to be compatible with the IAEA and the DOT regulations and to include additional staff-initiated administrative, editorial, or clarification changes. If the rulemaking plan is approved by the Commission, the NRC staff plans to hold public meetings at the NRC headquarters before and after development of the regulatory basis document to gather information from external stakeholders.

#### BACKGROUND:

In staff requirements memorandum for SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (Accession No. ML16034A441 in the NRC's Agencywide Documents Access and Management System (ADAMS)), the Commission directed the staff to provide a streamlined rulemaking plan in the form of a SECY paper that would request Commission approval to initiate all rulemakings not already explicitly delegated to the staff as a staff-delegated rulemaking. Accordingly, this paper requests approval to initiate a rulemaking related to revising 10 CFR Part 71 to be compatible with IAEA and DOT regulations along with additional NRC staff-initiated administrative, editorial, or clarification changes.

The IAEA periodically revises its regulations related to transportation of radioactive material to reflect scientific and technical advances and the knowledge gained through operational experience. Because the DOT and the NRC co-regulate transportation of radioactive materials in the United States, the NRC and DOT have historically coordinated to harmonize their respective regulations to these IAEA revisions through the rulemaking process. The roles of the DOT and the NRC in the co-regulation of the transportation of radioactive materials are documented in a Memorandum of Understanding (44 FR 38690; July 2, 1979).

In the NRC's previous 10 CFR Part 71 harmonization rulemaking, published in the *Federal Register* on June 12, 2015 (80 FR 33988, corrected on August 14, 2015 (80 FR 48683)), the Commission stated that NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with DOT. Accordingly, the staff, in coordination with the DOT, is currently reviewing the extent of harmonization needed based on the latest revision of SSR-6 (2012 Edition), along with an additional proposed revision estimated to be published by 2018.

#### DISCUSSION:

##### Title

Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements

##### Estimated Schedule

Initiate regulatory basis phase – February 2017.<sup>1</sup>

Complete regulatory basis that includes preliminary proposed rule language – January 2019.

Provide the proposed rule to the Commission – June 2019.

Provide the final rule to the Commission – June 2020.

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<sup>1</sup> Initiation of regulatory basis to begin 4 months following Commission approval.

### Priority

This is a high priority rulemaking activity using the Common Prioritization of Rulemaking (CPR) methodology that uses factors that are based on the NRC's Strategic Plan. The CPR methodology factors include the relative interest of the NRC, Congress, or other governmental bodies as well as members of the public, non-governmental organizations, the nuclear industry, vendors, and suppliers.

This activity responds to specific direction from the Commission in the previous 10 CFR Part 71 final rule published June 12, 2015 (80 FR 33988), wherein the Commission acknowledged issuance of the 2012 SSR-6 revision, and stated that the NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with DOT. Since then the NRC staff has been working with the DOT to identify and evaluate gaps that would be closed by the rulemaking. This activity also contributes toward the NRC's safety goal, safety strategies, and multiple cross-cutting strategies for regulatory effectiveness and openness. In addition, there is a moderate level of interest in this rulemaking activity from industry and stakeholders.

### Description and Scope

The NRC staff is proposing to revise 10 CFR Part 71 regulations for packaging and transportation of radioactive material. These revisions will make the NRC regulations consistent with the 2012 Edition along with another proposed subsequent revision of the IAEA's "Regulations for the Safe Transport of Radioactive Material," SSR-6, and DOT regulations. SSR-6 represents an international consensus set of requirements that provides a high level of safety in the packaging and transportation of radioactive materials and provides a basis and framework that facilitates the development of internationally consistent regulations. Internationally and domestically consistent regulations for the transportation and packaging of radioactive material reduce impediments to trade, facilitate international cooperation, and can reduce risks associated with the import and export of radioactive material. The scope of changes would include revisions to the existing requirements in 10 CFR Part 71 as well as conforming changes to related NRC standard review plans (e.g., NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material," and NUREG-1617, "Standard Review Plan for Transportation Packages for Spent Nuclear Fuel").

The NRC staff is considering two alternatives for this proposed rule:

#### Alternative 1: The No-Action Alternative

This alternative would maintain the status quo. Under Alternative 1, the NRC would make no changes to the current regulations in 10 CFR Part 71, and there would be no costs or benefits. Alternative 1 would avoid costs that the rule would impose; however, it would result in greater divergence between the international standards and domestic regulations. Specifically, DOT plans to move forward with their rulemaking and under Alternative 1 the NRC, DOT, and international regulations would not be compatible. Differences in domestic and international regulations can create situations where licensees may find it more complicated and expensive to transport, import, or export radioactive material, thus, inhibiting trade. Under this alternative, there would be no changes to the current level of protection for public health and safety. Also, there would be no changes made to improve regulatory efficiency that could result in benefits to certain segments of the transportation industry.

## Alternative 2: IAEA-DOT/NRC Compatibility Including NRC Staff-Initiated Changes

This alternative would harmonize and maintain compatibility of the NRC regulations with SSR-6 and with changes implemented by the DOT, and include any additional NRC staff-initiated changes. These NRC staff-initiated changes would include revisions to clarify existing rule text and make administrative or editorial changes as appropriate. In addition to soliciting public comment on the regulatory basis document and proposed rule, the staff would have public meetings at NRC headquarters before and after development of the regulatory basis document to gather information from stakeholders to help assess the extent of rulemaking needed for harmonization and any staff-initiated changes.

The estimate for resources in the enclosure is for Alternative 2. The recommendation is to proceed with Alternative 2 to harmonize the NRC regulations with the IAEA and the DOT regulations, and include any NRC staff-initiated administrative, editorial, or clarification changes.

### Relationship of the Work to the NRC's Strategic Plan

These revisions will make the NRC regulations compatible with the 2012 Edition and a potential subsequent revision of the IAEA's "Regulations for the Safe Transport of Radioactive Material," SSR-6, and DOT regulations. The SSR-6 represents an accepted set of standards that provides a high level of safety and facilitates the development of internationally consistent regulations. Through harmonization with SSR-6 and the DOT regulations, both the NRC Strategic Goal of safety and the transportation regulations will benefit from progress made by the IAEA to enhance the safety of packaging and transporting radioactive material.

### Cost and Benefits

The proposed action is estimated to involve a low magnitude of costs based on the cost and benefits analysis that was performed in the last regulatory analysis for compatibility with the IAEA regulations, "Regulatory Analysis for Final Rulemaking - Compatibility with IAEA Transportation Standards (10 CFR Part 71)," (ADAMS Accession No. ML14031A489). The proposed action is estimated to provide the following benefits: 1) harmonization with international and DOT standards would achieve and maintain NRC regulatory efficiency, and 2) consistency between domestic and international transportation regulations would reduce costs to industry and improve operations because radioactive material could more easily be imported and exported. The specific changes and specific cost and benefits that could be implemented are not yet known and would be evaluated during the regulatory basis phase.

### Cumulative Effects of Regulation

In a preliminary assessment of the cumulative effects of regulation, there are no other ongoing NRC activities that would impact this proposed rulemaking. The NRC staff and DOT would work to assess the extent of rulemaking needed for harmonization of the domestic regulations with the IAEA regulations and any staff-initiated changes.

### Agreement State Considerations

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC transport regulations.

The specific changes in 10 CFR Part 71 are not yet known and would be evaluated during the regulatory basis phase. During the proposed rule phase the NRC would analyze the proposed rule in accordance with the procedure established within Part III, “Categorization Process for NRC Program Elements,” of Handbook 5.9 to Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (ADAMS Accession No. ML041770094) and coordinate the rulemaking as appropriate consistent with NRC policy and other guidance documents. The Agreement States normally have 3 years from the effective date of the final rule to adopt compatible regulations or other legally binding requirements. However, under certain circumstances, the effective dates for both the NRC licensees and Agreement State licensees can be the same, or less than a 3-year timeframe for Agreement State implementation of the regulatory provisions.

### Backfitting and Issue Finality

The staff does not expect that the backfit rules (§§ 50.109, 70.76, 72.62, or 76.76) and the issue finality provisions in 10 CFR Part 52 would apply to this proposed rule, because this proposed rule is not expected to establish any provisions that would impose backfits as defined in 10 CFR Chapter I. The proposed rule would revise various 10 CFR Part 71 provisions. There are no backfitting or issue finality provisions in 10 CFR Part 71. Therefore, applicants, licensees, or holders of a certificate under 10 CFR Part 71 would not be protected by backfitting or issue finality provisions. In addition, the proposed rule as currently envisioned would not affect entities protected by backfit rules and issue finality provisions with respect to the activities subject to backfitting or issue finality protection.

### Guidance

The staff estimates that two guidance documents would be revised in parallel with the rulemaking: NUREG-1609, “Standard Review Plan for Transportation Packages for Radioactive Material,” and NUREG-1617, “Standard Review Plan for Transportation Packages for Spent Nuclear Fuel.”

### Advisory Committee on Reactor Safeguards (ACRS) Review

The staff requests Commission direction on whether ACRS review is warranted. The initial review of the harmonization of 10 CFR Part 71 with the IAEA regulations has indicated no significant technical differences that would warrant a formal technical briefing to the ACRS. However, after further review, the NRC staff would engage in discussions with the ACRS to determine if an ACRS review is necessary.

At this time, the recommendation is that an ACRS review is not warranted.

Committee to Review Generic Requirements (CRGR) Review

The staff does not believe CRGR review is necessary for the following reasons: there is no provision in 10 CFR Part 71 for backfit protections or issue finality, and there are no protected regulated entities under 10 CFR Part 71.

Analysis of Legal Matters

The Office of the General Counsel has reviewed the rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

COMMITMENT:

If the Commission approves initiation of the rulemaking, the staff will maintain the proposed rule in the CPR.

RECOMMENDATION:

The NRC staff recommends that the Commission approve initiation of a rulemaking related to the harmonization of 10 CFR Part 71 with the IAEA and the DOT regulations.

The staff's recommendation is that there is not a need for an ACRS review, consistent with the discussion in subsection "Advisory Committee on Reactor Safeguards (ACRS) Review."

RESOURCES:

The enclosure includes an estimate of the resources needed to complete this rulemaking. Resource estimates in the enclosure are not publicly available.

COORDINATION:

The Office of the General Counsel has no legal objection to this action. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

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Enclosure:  
Resources

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Enclosure:  
Resources

**ADAMS Accession Number: ML16158A162**

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