



POLICY ISSUE

(Notation Vote)

October 30, 2020

SECY-20-0102

FOR: The Commissioners

FROM: Margaret M. Doane
Executive Director for Operations

SUBJECT: PROPOSED RULE: HARMONIZATION OF TRANSPORTATION
SAFETY REQUIREMENTS WITH INTERNATIONAL ATOMIC ENERGY
AGENCY STANDARDS (RIN 3150-AJ85; NRC-2016-0179)

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish in the *Federal Register* for public comment the enclosed proposed rule (Enclosure 1) and draft implementation guidance related to U.S. Nuclear Regulatory Commission (NRC) regulations for the domestic packaging and transportation of radioactive material. This rule will harmonize the NRC's regulations with International Atomic Energy Agency (IAEA) standards and conform to U.S. Department of Transportation (DOT) regulations. Additionally, the proposed rule would include administrative, editorial, and clarifying changes, including proposed changes to certain Agreement State compatibility category designations. This paper addresses no new commitments.

SUMMARY:

The staff recommends that the NRC amend its regulations for the packaging and transportation of radioactive material, in an effort coordinated with the DOT. The NRC has historically revised its transportation safety regulations to ensure harmonization with IAEA standards. These changes are necessary to maintain a consistent regulatory framework with the DOT for the domestic packaging and transportation of radioactive material and to ensure general accord

CONTACT: George M. Tartal, NMSS/REFS
301-415-0016

Bernard H. White, NMSS/DFM
301-415-6577

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with IAEA standards. Concurrently, the staff would issue for public comment Draft Regulatory Guide (DG)-7011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20072M234), which would become Revision 3 to Regulatory Guide (RG) 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material."

BACKGROUND:

On June 12, 2015, the NRC, in consultation with the DOT, published a final rule that amended the NRC's regulations for the packaging and transportation of radioactive material (80 FR 33988; June 12, 2015). These amendments made conforming changes to the NRC's regulations based on the standards of the IAEA. That final rule, in combination with a DOT final rule (79 FR 40589; July 11, 2014), amending Title 49 of the *Code of Federal Regulations* (49 CFR), brought U.S. regulations into general accord with the 2009 Edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1). The IAEA has since updated its standards for the transport of radioactive material in Specific Safety Requirements No. 6 (SSR-6), "Regulations for the Safe Transport of Radioactive Material" (2012 and 2018 Editions). In the 2015 final rule, the Commission stated that the NRC would consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT.

The roles of the DOT and the NRC in the coregulation of the transportation of radioactive materials are documented in a memorandum of understanding (44 FR 38690; July 2, 1979). Because of the coregulation of the transportation of radioactive materials in the United States, the NRC and the DOT have historically coordinated to harmonize their respective regulations with the IAEA revisions through the rulemaking process. The NRC staff has engaged with the DOT staff to identify and evaluate gaps between the NRC's regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Materials," and the updated IAEA standards in SSR-6, 2018 Edition. The enclosed proposed rule would close these gaps, where warranted. The DOT is undertaking similar action to harmonize its regulations for the transportation of radioactive material in 49 CFR Parts 107 and 171–180 with the 2018 Edition of SSR-6. The DOT has not yet issued its proposed rule. The NRC staff will continue to coordinate with the DOT throughout the rulemaking process to ensure the final NRC and DOT rules are consistent and, if possible, synchronize publication of proposed and final rules.

In SECY-16-0093, "Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements," dated July 28, 2016, the staff requested Commission approval to initiate this rulemaking. The Commission approved the staff's recommendation through the staff requirements memorandum to SECY-16-0093, dated August 19, 2016. On April 12, 2019, the NRC noticed the regulatory basis for the proposed rule in the *Federal Register* and requested public comments (84 FR 14898; April 12, 2019). The NRC received seven public comment submissions on the regulatory basis. The NRC considered these comments in preparing the proposed rule, as described in Enclosure 1.

DISCUSSION:

Overview of Proposed Changes to Transportation Safety Regulations

The staff is proposing to amend NRC regulations to harmonize and ensure general accord with IAEA SSR-6 (2018 Edition). These revisions would also be consistent with DOT hazardous

materials regulations and maintain a consistent framework for the domestic packaging and transportation of radioactive material. In addition, the proposed rule would revise 10 CFR Part 71 to include administrative, editorial, and clarifying changes, including proposed changes to certain Agreement State compatibility category designations. In the proposed rule, Issues 1, 4.1, 4.2, 5, 8, and 9 harmonize with IAEA standards; Issues 6, 7, 10, 11, and 15.3 harmonize with IAEA and ensure compatibility with DOT regulations; and Issues 12, 13, 14, 15.1, 15.2, 15.4 and 15.5 are NRC initiated changes. As discussed in the proposed rule, the staff reviewed all changes to the IAEA standard since the last NRC harmonization effort in 2015 and decided not to adopt some changes. The proposed rule would apply to (1) NRC licensees authorized by a Commission-issued specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, or transports the material outside of the site of usage as specified in the NRC license, or transports that material on public highways; (2) holders of, and applicants for, a certificate of compliance under 10 CFR Part 71; and (3) holders of a 10 CFR Part 71 quality assurance program approval.

Specifically, the staff is proposing to amend 10 CFR Part 71 or change Agreement State compatibility category designations as follows:

- Revise the fissile material exemptions in 10 CFR 71.15, "Exemption From Classification as Fissile Material," to be compatible with IAEA SSR-6 (Issue 1).
- Change the unit of measure for insolation in 10 CFR 71.71(c)(1) and require insolation as an initial condition for the tests for hypothetical accident conditions in 10 CFR 71.73(b), to be compatible with IAEA SSR-6 (Issues 4.1 and 4.2).
- Define the term "radiation level" in 10 CFR 71.4, "Definitions," to clarify that it has the same meaning as "dose equivalent rate," to be compatible with IAEA SSR-6 (Issue 5).
- Remove the leaching test requirement from 10 CFR 71.77, "Qualification of LSA-III Material," for Low Specific Activity-III material, and make conforming changes to 10 CFR 71.4 and 10 CFR 71.100, "Criminal Penalties," to be compatible with IAEA SSR-6 (Issue 6).
- Add a definition to 10 CFR 71.4 for a new category of large surface contaminated objects, to be compatible with IAEA SSR-6 (Issue 7).
- Add a new requirement for a uranium hexafluoride cylinder plug to ensure it remains leak tight and prevents water ingress, to be compatible with IAEA SSR-6 (Issue 8).
- Clarify existing requirements in 10 CFR 71.43(d) related to the evaluation of the effects of aging and require a description of the maintenance program for the packaging, to be compatible with IAEA SSR-6 (Issue 9).
- Update the regulations related to continued fabrication and use of packages approved under previous regulations, to be compatible with IAEA SSR-6 (Issue 10).
- Add a design requirement to ensure adequate ullage (unfilled space) in a package designed to contain liquids, to be compatible with IAEA SSR-6 (Issue 11).

- Clarify 10 CFR 71.106(b) to require a biennial report when no changes are made to the NRC-approved quality assurance program during the reporting period (Issue 12).
- Correct the inconsistencies between the mass limits and package restrictions for fissile material general licenses in 10 CFR 71.22, “General License: Fissile Material,” and 10 CFR 71.23, “General License: Plutonium-Beryllium Special Form Material” (Issue 13).
- Remove an inconsistency in 10 CFR 71.22 for fissile material in packages with low concentrations of uranium-233 (Issue 14).
- Remove duplicative reporting requirements in 10 CFR 71.95, “Reports” (Issue 15.1).
- Revise the definition of “Low Specific Activity Material” in 10 CFR 71.4 to be consistent with 10 CFR 71.15 (Issue 15.2).
- Add new radionuclides to Tables A-1 and A-2 of Appendix A, “Determination of A₁ and A₂,” to 10 CFR Part 71 to be compatible with IAEA SSR-6 and the DOT regulations at 49 CFR 173.435, “Table of A1 and A2 Values for Radionuclides,” and 49 CFR 173.436, “Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides” (Issue 15.3).
- Revise the Agreement State compatibility categories for the quality assurance program requirements in 10 CFR 71.101, 71.103, 71.105, 71.106, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, and 71.137, and the reporting requirements in 10 CFR 71.95 (Issue 15.4).
- Remove redundant advance notification requirements for spent fuel between 10 CFR Part 71 and 10 CFR Part 73, “Physical Protection of Plants and Materials” (Issue 15.5).

Regulatory Analysis

The staff prepared a draft regulatory analysis (Enclosure 2) to determine anticipated costs and benefits associated with implementing the new requirements and the development of, or modifications to, NRC guidance. The regulatory analysis shows that the staff’s recommendation for rulemaking and guidance development, quantitatively, is overall cost beneficial to the industry but not cost beneficial to the Government. The analysis determines that the proposed rule alternative and associated guidance would result in a total net overall cost of (\$542,909). Of that amount, the NRC is expected to incur a cost of (\$1,489,808), Agreement States are expected to incur a cost of (\$2,408,083), licensees would incur a savings of \$5,929,424, and certificate of compliance holders would incur a cost of (\$2,574,442).

The regulatory analysis also considers qualitative benefits of the proposed requirements. Important qualitative benefits include harmonizing the NRC regulations with the IAEA’s safety standards, which minimizes potential international commerce disruption and helps to ensure that international obligations are met (e.g., for air transport, the IAEA transport standards serve as the basis for the International Civil Aviation Organization Technical Instructions, as they relate to radioactive material, with which the United States must comply according to the Convention on International Civil Aviation, also known as the Chicago Convention), and

assuring consistency between the NRC's regulations and the DOT's regulations for domestic transportation of radioactive materials.

In the staff's judgement these combined qualitative and quantitative benefits of the rule outweigh its costs. Therefore, the staff recommends going forward with the rulemaking.

Cumulative Effects of Regulation

The staff is considering the cumulative effects of regulation by engaging with external stakeholders throughout the development of the proposed rule and related regulatory activities. The staff published the regulatory basis in the *Federal Register* (84 FR 14898; April 12, 2019). In addition, the staff held a public meeting on April 30, 2019, to facilitate public comments on the regulatory basis. The staff will also conduct a public meeting during the comment period for the proposed rule.

The staff has coordinated with the Agreement States during the development of the proposed rule to ensure they are informed of the proposed amendments to compatibility categories. The staff also discussed the proposed rule with the Agreement States Standing Committee for Compatibility and has addressed the committee's comments and recommendations.

Implementing Guidance

The staff plans to publish DG-7011 for public comment in conjunction with the proposed rule.

DG-7011 would update the guidance in RG 7.9, Revision 2, issued March 2005 (ADAMS Accession No. ML050540321). RG 7.9 is intended for use by applicants preparing applications for approval of Type B and fissile material transportation packages. This guidance describes a method that is acceptable to the staff for complying with the agency's regulations in 10 CFR Part 71. As a guidance document, RG 7.9 and the changes to that guidance in DG-7011 would not establish additional requirements, and applicants may propose alternative ways for demonstrating compliance with the regulations.

Backfitting and Issue Finality Considerations

The staff has determined that the backfit rule (10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, or 10 CFR 76.76) and the issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," do not apply to the proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Some licensees that are within the scope of the backfit rule (e.g., a power reactor or a fuel fabrication facility) transport radioactive material from their own facilities. Those backfitting and issue finality provisions apply to activities directly regulated under those parts, and do not apply to activities regulated under other parts that do not include backfitting or issue finality provisions. The exception to this general principle is where the activity regulated under other parts that do not include backfitting or issue finality provisions is an inextricable part of the regulated activity within the scope of backfitting or issue finality. Preparing packages for transport is not an inextricable part of the procedures or organization required to design, construct or operate a facility as licensed under 10 CFR Part 50, 52, 70, 72, or 76; rather, it is a separate activity that these licensees may choose to undertake. The scope of the proposed rule would not propose changes to any of those facilities or plants' activities for which the backfit rule applies. In developing this determination, the staff followed guidance in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,"

dated September 20, 2019, and NUREG-1409, "Backfitting Guidelines," draft Revision 1, issued March 2020.

Other Related Topics

The staff continues to engage its stakeholders on regulatory issues related to the use, including transportation, of accident tolerant fuel (ATF) and high-assay low-enriched uranium (HALEU) in light-water and advanced reactors. HALEU refers to uranium enriched to above 5 and below 20 weight percent uranium-235. To increase regulatory stability and certainty for these issues, the staff developed the "Project Plan to Prepare the U.S. Nuclear Regulatory Commission for Efficient and Effective Licensing of Accident Tolerant Fuels," issued October 2019 (ADAMS Accession No. ML19301B166). The project plan describes the NRC's approach to license the use of ATF throughout the entire fuel cycle, including enrichment, fabrication, in-reactor use, transportation, and interim or long-term storage. As part of the project plan, the staff evaluated whether revisions to Part 71 may be necessary given the expected use of ATF and HALEU in the future and concluded that no changes to the requirements in 10 CFR Part 71 are necessary at this time. Although 10 CFR Part 71 would be used to certify transportation package designs for ATF and HALEU, the staff has not directly considered ATF and HALEU in this rulemaking.

RECOMMENDATIONS:

The staff recommends that the Commission approve the enclosed proposed rule (Enclosure 1) for publication in the *Federal Register*.

If the Commission approves, the staff will complete the following six activities related to the publication of the proposed rule:

- (1) The staff will publish in the *Federal Register* the proposed rule, including notice of DG-7011, and provide a 75-day public comment period for the proposed rule and DG-7011.
- (2) The staff will make publicly available the draft regulatory analysis (Enclosure 2) and the draft environmental assessment (Enclosure 3) for the proposed rule.
- (3) The staff will submit information collection requirements to the Office of Management and Budget for its review and approval on or immediately after the date of publication of the proposed rule in the *Federal Register*.
- (4) The Office of Congressional Affairs will inform the appropriate congressional committees.
- (5) The staff will work with the Office of Public Affairs on an appropriate public communication when the NRC publishes the proposed rule in the *Federal Register*.
- (6) The staff will hold a public meeting during the comment period for the proposed rule.

RESOURCES:

This is a medium-priority rulemaking. The Spent Fuel Storage and Transportation Business Line includes resources for the rulemaking for fiscal years 2021 and 2022. The staff will address resources beyond fiscal year 2022, if needed, through the planning, budget, and

performance management process and will prioritize these activities in a manner consistent with the current Common Prioritization of Rulemaking process. Enclosure 4 includes an estimate of the NRC resources needed to complete this rulemaking. Resource estimates in Enclosure 4 are not publicly available.

COORDINATION:

The Office of the General Counsel has no legal objection to the publication of the proposed rule. The Office of the Chief Financial Officer reviewed this package and has no concerns with the estimated resources in Enclosure 4.

In a letter dated May 18, 2020 (ADAMS Accession No. ML20135H271), the Advisory Committee on Reactor Safeguards determined that its review of the proposed rule is not necessary. The staff will provide an information copy of the *Federal Register* notice to the committee after publication.

Margaret M. Doane

Digitally signed by Margaret M.
Doane
Date: 2020.10.30 18:31:37 -04'00'

Margaret M. Doane
Executive Director
for Operations

Enclosures:

1. Proposed Rule
2. Draft Regulatory Analysis
3. Draft Environmental Assessment
4. Estimated Rulemaking
Resources (not publicly available)

SUBJECT: PROPOSED RULE: HARMONIZATION OF TRANSPORTATION SAFETY REQUIREMENTS WITH INTERNATIONAL ATOMIC ENERGY AGENCY STANDARDS (RIN 3150-AJ85; NRC-2016-0179) DATED October 30, 2020

ADAMS Accession Number: ML20101F914 (pkg) WITS: SRM-S16-0093-3 *via email

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NAME	GTartal	ALoveBlair*	JCai*	CBladey*	JMcKirgan*
DATE	4/3/2020	4/9/2020	4/15/2020	4/22/2020	4/20/2020
OFFICE	NMSS/ MCAB:BC	NMSS/IOB: BC	NMSS/ NARAB:BC	NMSS/ SALP:BC	NMSS/ CTCFB:BC
NAME	JRubenstone*	APearson*	KArmstrong*	LCuadrado*	YDiaz- Sanabria*
DATE	4/20/2020	4/22/2020	4/20/2020	4/19/2020	4/21/2020
OFFICE	NMSS/MSB:BC	NMSS/DFM:DD	NMSS/ MSST:DD	NMSS/ REFS:DD	OCIO/ GEMS:BC
NAME	MRahimi*	AKock*	MLayton*	JTappert*	DCullison*
DATE	4/20/2020	4/22/2020	4/14/2020	4/21/2020	4/20/2020
OFFICE	RES/DE:BC	RES/DE:DD	OE:D	OCFO/DOB:DD	NRR:DD
NAME	TBoyce*	LLund*	GWilson*	RAllwein*	AVeil*
DATE	4/21/2020	4/17/2020	5/22/2020	5/13/2020	5/15/2020
OFFICE	OGC	QTE	NMSS:D	OEDO	
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DATE	8/13/2020	8/24/2020	10/2/2020	10/30/20	

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