

## **RULEMAKING ISSUE** **(Affirmation)**

September 24, 2014

SECY-14-0100

FOR: The Commissioners

FROM: Mark Satorius  
Executive Director for Operations

SUBJECT: FINAL RULE: REVISIONS TO TRANSPORTATION SAFETY  
REQUIREMENTS AND HARMONIZATION WITH  
INTERNATIONAL ATOMIC ENERGY AGENCY  
TRANSPORTATION REQUIREMENTS (RIN 3150-AI11)

PURPOSE:

To request Commission approval to publish a final rule (Enclosure 1) in the *Federal Register* that would amend Part 71 of title 10 of the *Code of Federal Regulations* (10 CFR), "Packaging and Transportation of Radioactive Material." Implementation of this rulemaking will not require any new, unbudgeted resources.

SUMMARY:

The final rule will amend the U.S. Nuclear Regulatory Commission's (NRC) regulations related to the packaging and transportation of radioactive material. This final rule, in consultation with the U.S. Department of Transportation (DOT), makes conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) regulations for the international transportation of radioactive material and maintains consistency with the DOT's regulations. Additionally, the final rule will: 1) revise quality assurance program requirements, 2) re-establish restrictions on material that qualifies for the fissile material exemption, 3) clarify the requirements that are applicable to a general license, 4) clarify the responsibilities of certificate holders and licensees in determining, before first use, the adequacy of transportation packaging, and 5) make other non-substantive changes such as correcting citation errors.

CONTACTS: Solomon Sahle, FSME/DILR  
301-415-3781

Daniel Huang, NMSS/SFST  
301-287-9234

### BACKGROUND:

Periodically, the IAEA revises its regulations related to transportation of radioactive material. The NRC evaluated changes in the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1) and identified a number of areas in 10 CFR Part 71 that needed to be revised to maintain compatibility with the IAEA's regulations.

Historically, the NRC has coordinated its revisions to 10 CFR Part 71 with the DOT, because the DOT and the NRC co-regulate transport of radioactive materials in the United States. 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 (MOU) (44 FR 38690; July 2, 1979). Consistent with this MOU, the NRC has coordinated its efforts with the DOT during this rulemaking, and representatives from the NRC and DOT have advised and consulted with one another. This final rule has been coordinated with DOT to ensure that consistent regulatory standards are maintained between NRC and DOT radioactive material transportation regulations, and to ensure coordinated publication of the final rules by both agencies. On July 11, 2014 the DOT published its final rule titled, "Hazardous Materials: Compatibility with the Regulations of the International Atomic Energy Agency" in the *Federal Register* (79 FR 40590) with an effective date of October 1, 2014, and a mandatory compliance date of July 13, 2015.

The staff sent the Commission a proposed rule to amend 10 CFR Part 71 on December 13, 2012 (SECY-12-0166). The Commission approved the proposed rule and it was published in the *Federal Register* on May 16, 2013 (78 FR 28988). The public comment period closed on July 31, 2013, and eight comment letters were received. Commenters included Federal agencies, States, licensees, industry organizations, and individuals. The staff finds that the comments did not warrant any changes to the rule's provisions as proposed.

### DISCUSSION:

The primary objective of this final rule is to maintain the compatibility of 10 CFR Part 71 with the IAEA's regulations in TS-R-1 and the DOT's regulations.

Revisions to maintain compatibility with the IAEA's and the DOT's regulations include the following:

- The final rule is changing the exemption for natural materials and ores containing naturally occurring radionuclides to be consistent with the international transport regulations by allowing natural materials and ores that have been processed to qualify for the exemption.
- The concept of processing ores for purposes other than radioactive material content is added to the provisions that apply to natural materials and ores in the exemptions for low-level materials in § 71.14, "Exemption for low-level materials."
- A definition of "contamination" corresponding to the definition in TS-R-1 is added to § 71.4, "Definitions." The following definitions in 10 CFR 71.4 are amended to reflect the

current definitions in TS-R-1: “Criticality Safety Index (CSI),” “Low Specific Activity (LSA) material,” and “Uranium—natural, depleted, enriched.”

- The NRC is adopting the use of the Class 5 impact test prescribed in the International Organization for Standardization’s (ISO) Document 2919, “Radiation protection—Sealed radioactive sources—General requirements and classification,” Second Edition (February 15, 1999), ISO 2919:1999(E), for special form radioactive material, provided the mass is less than 500 grams.
- The NRC is incorporating by reference (A) ISO Document 2919, and (B) ISO Document 9978, “Radiation protection—Sealed radioactive sources—Leakage test methods,” First Edition (February 15, 1992), ISO 9978:1992(E).
- The NRC is changing some values in Tables A-1, “A1 and A2 Values for Radionuclides,” A-2, “Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides,” and A-3, “General Values for A<sub>1</sub> and A<sub>2</sub>,” of Part 71 Appendix A to align with IAEA’s TS-R-1 values.

As summarized below, the final rule also makes several NRC-initiated changes, the more significant of which are the following:

In 10 CFR 71.101, “Quality assurance requirements,” paragraph (a) is revised by deleting its first reference to licensees, in order to clarify that with respect to the design, fabrication, testing, and modification of packaging, only certificate holders and applicants for a Certificate of Compliance are subject to quality assurance requirements. Note that under 71.101(a), as revised, licensees are still subject to quality assurance requirements with respect to their use of packages when shipping radioactive material, consistent with the existing 71.101(c)(1).

A new section 71.106, “Changes to a quality assurance program,” allows some changes to a quality assurance program to be made and implemented without obtaining the prior approval of the NRC. Such changes include those that do not reduce commitments to the NRC, such as those that involve administrative improvements and editorial changes. Previously, all changes, no matter how insignificant, had to be approved by the NRC before they could be implemented. Additionally, the NRC will no longer require the renewal of quality assurance program approvals. These changes are expected to increase the efficiency of the NRC’s oversight of quality assurance programs for transportation packages.

In 10 CFR 71.15, “Exemption from classification as fissile material,” paragraph (d) is revised to reinstate a restriction on an exemption pertaining to uranium, enriched in the uranium-235 isotope, to a maximum of 1 percent. More specifically, to ensure that criticality events do not occur while such material is being transported, this exemption is revised by adding a provision that in order to qualify for the exemption, the material must be distributed homogeneously within the transportation package, and not form a lattice arrangement.

In 10 CFR 71.17, “General license: NRC-approved package,” paragraph (c) is revised to clarify the requirements that are applicable to general licensees. Similar requirements in 10 CFR 71.21, “General license: Use of foreign approved package,” are changed by revising paragraph

(d) to clarify the requirements that are applicable to general licensees. Additionally, paragraph (d)(2) is revised by deleting its second sentence, which provided an exemption from quality assurance provisions in Part 71, subpart H for design, construction, and fabrication activities. Because such quality assurance provisions are not applicable to a general licensee, the exemption was found to be superfluous.

In 10 CFR 71.85, “Preliminary determination,” paragraphs (a), (b), and (c) are revised by replacing “licensee” with “certificate holder.” This change makes the certificate holders who manufacture the transportation packages, rather than the licensees who use them, responsible for making the required preliminary determinations. The NRC experience is that these determinations are performed by the certificate holders, and this change will thus make the requirements consistent with current practice. Furthermore, only certificate holders will have a quality assurance program approval that will allow them to conduct the required tests under an approved quality assurance program. Paragraph (d) is added to 10 CFR 71.85 in order to state the responsibilities of licensees using a package for transportation. Although certificate holders are required to make the preliminary determinations under paragraphs (a), (b), and (c), licensees remain responsible for ensuring that these determinations have been made before their first use of the packaging.

The final rule is consistent with the NRC’s strategic goal for safety and the associated strategic outcomes. By maintaining consistency with the international regulations and the DOT regulations, the NRC continues to ensure adequate protection of the public health and safety. By reinstating a restriction on an exemption pertaining to uranium, enriched in the uranium-235 isotope, to a maximum of 1 percent, the NRC reduces the likelihood of inadvertent criticality events while such material is being transported. The changes to regulations regarding quality assurance programs allow NRC oversight of the quality assurance programs to be more efficient so that resources can be redirected towards activities that provide a greater contribution towards reducing the risk of transportation incidents.

### Public Comment Analysis

There was a range of stakeholder views concerning the proposed rule. Most commenters supported all or part of the proposed rule. Two commenters voiced general support of the NRC’s efforts to harmonize 10 CFR Part 71 with the DOT’s and the IAEA’s regulations. Three other commenters indicated support for the proposed revisions to the definition of LSA group I, with two of those commenters stating their view that this proposed revision corrected a longstanding error in the NRC’s regulations that created an incompatibility with existing DOT regulations. Other commenters voiced general support for the proposed revisions to quality assurance requirements and for provisions related to exempted low-level material. The comments and responses have been grouped into five topical areas: New and Revised Definitions, Exemptions for Low-level Materials, Quality Assurance, Technical Requirements, and Other.

A summary of the comments received on the proposed rule and the NRC’s responses are found in Section IV, “Public Comment Analysis,” of the draft *Federal Register* notice.

### Guidance

Regulatory Guide (RG) 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," has been updated to reflect the changes being made to the quality assurance program requirements. One commenter indicated additional clarification of the terms "homogeneity" and "lattice arrangement" in § 71.15(d) would be beneficial. The staff has provided the clarification in section D.1 of the draft final rule *Federal Register* notice. The draft revised RG 7.10 was published for comment on May 16, 2013 (78 FR 29016). The final revision of RG 7.10 will be issued concurrently with the publication of the final rule, if approved by the Commission.

### AGREEMENT STATE COMPATIBILITY:

A copy of the draft final rule *Federal Register* notice (FRN) was provided to the Agreement States for an early opportunity to review, and two Agreement States (Washington and Utah) provided comments. The State of Washington's comment favors the proposed revisions to 10 CFR Part 71, and stated that it is important to keep 10 CFR Part 71 up-to-date, to ensure compatibility with the model transportation regulations of the IAEA, and to ensure consistency with the DOT regulations. The State of Utah's comments were limited to issues regarding the DOT's regulations in 49 CFR, and these comments were forwarded to the DOT for its consideration prior to the DOT's issuance of its final rule.

The NRC staff has analyzed the final rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, "Categorization Process for NRC Program Elements." The final rule has different compatibility designations depending on the specific sections of the rule. The compatibility determination for the final rule is addressed in Section XIV of the final rule Statements of Consideration on Agreement State Compatibility.

The Standing Committee on Compatibility reviewed the final rule and agreed that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States. The Committee and the NRC staff have reached agreement on the compatibility designations that are reflected in the draft final rule.

### Public Meeting on Implementation of the NRC's Final Rule

On July 9, 2014, the NRC staff conducted a category 3 public Webinar on implementation of the final NRC rule to discuss any cumulative effect of regulation concerns. No such concerns were identified during the Webinar.

### COMMITMENTS:

The NRC staff will make the final revised RG 7.10 publicly available concurrent with the publication of the final rule.

RECOMMENDATIONS:

That the Commission:

1. Approve publication of the final rule in the *Federal Register* (Enclosure 1).
2. Certify that this final rule, if adopted, will not have significant impact on a substantial number of small entities, to satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b). This certification is included in the enclosed *Federal Register* notice.
3. Note:
  - a. 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).
  - b. A final Regulatory Analysis has been prepared for this final rule (Enclosure 2).
  - c. A final Environmental Assessment has been prepared for this final rule (Enclosure 3).
  - d. The NRC staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 (5 U.S.C 804(2)) and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed.
  - e. The appropriate Congressional committees will be informed.
  - f. A press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the Federal Register.
  - g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

The resources to complete the rule and revise the implementation guidance are estimated to be less than two full time equivalents. The resources are included in the FY 2015 budget request for the Spent Fuel Storage and Transportation Business Line.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rule. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

***/RA Michael F. Weber/***

Mark Satorius  
Executive Director  
for Operations

Enclosures:

1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment

COORDINATION:

The Office of the General Counsel has no legal objection to the final rule. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

***/RA Michael F. Weber/***

Mark Satorius  
Executive Director  
for Operations

## Enclosures:

1. *Federal Register* notice
2. Regulatory Analysis
3. Environmental Assessment

**ML14237A375/WITS 201300037**

<b>OFC</b>	RPMB/DILR	RPMB/DILR	D:DILR	D/NMSS
<b>NAME</b>	SSahle	JDanna	CMiller	CHaney
<b>DATE</b>	8/29/14	9/4/14	9/9/14	3/14/14
<b>OFC</b>	OCFO	OIS	ADM	D/OE
<b>NAME</b>	JDyer	KBenney	CBladey	RZimmerman
<b>DATE</b>	3/8/14	3/13/14	3/12/14	3/10/14
<b>OFC</b>	OGC	Tech Editor	D/FSME	EDO
<b>NAME</b>	PMoulding	PTressler	BHolian	MSatorius
<b>DATE</b>	8/13/14	9/11/14	9/16/14	9/24/14

**OFFICIAL RECORD COPY**