

RULEMAKING ISSUE NOTATION VOTE

December 13, 2012

SECY-12-0166

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED 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 proposed rule, in the *Federal Register*, that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71. The proposed amendments would revise the regulations for the packaging and transportation of radioactive material to: make the U.S. Nuclear Regulatory Commission (NRC) regulations compatible with the 2009 edition of the International Atomic Energy Agency's (IAEA) transportation standards, "Regulations for the Safe Transport of Radioactive Material," (TS-R-1), maintain consistency with changes in the U.S. Department of Transportation (DOT) regulations, and make other changes to the requirements for the packaging and transportation of radioactive material.

SUMMARY:

The NRC is proposing revisions to the transportation safety requirements in 10 CFR Part 71 to reflect acquired knowledge and experience from NRC and from IAEA's transportation standards. The NRC periodically updates the transportation regulations in 10 CFR Part 71 to reflect the changes in the TS-R-1. Coordination with the DOT is necessary before these periodic updates, because both the DOT and the NRC have regulatory responsibility for the transport of nuclear material in the United States. The proposed rule would also make other changes to 10 CFR Part 71.

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These other changes include amendments to enhance the efficiency of the regulation for quality assurance (QA) programs and revising the fissile material exemption to ensure that material qualifying for the exemption would be subcritical and that criticality would not be a potential hazard for this material during transportation under a general license. The staff has prepared a proposed rule (Enclosure 1) that would amend 10 CFR Part 71 to make changes to the NRC regulations for the packaging and transportation of radioactive material.

BACKGROUND:

On January 26, 2004 (69 FR 3698), the NRC promulgated a final rule that made 10 CFR Part 71 compatible with the IAEA transportation standards and made changes in the fissile material exemption requirements. The 2004 rulemaking harmonized the NRC regulations with the 1996 edition (revised) of TS-R-1 (June 2000). The IAEA is revising its regulations on an approximate 2-year cycle. The DOT is the lead agency for the regulation of transportation of hazardous material in the United States, and has regulatory responsibility along with the NRC for the transportation of radioactive material. The DOT is conducting a rulemaking to harmonize the DOT hazardous materials regulations (HMR) at Title 49 of the CFR (49 CFR) Parts 171 through 178 with changes contained in the 2009 edition of TS-R-1 and to make other changes.

The enclosed proposed rule would harmonize the regulations at 10 CFR Part 71 with changes contained in the 2009 edition of TS-R-1 and with the proposed changes to the DOT HMR (76 FR 50332; August 12, 2011). The parallel NRC and DOT rulemakings are intended to be consistent for those areas that are common in the two sets of regulations. The proposed changes would increase the compatibility of 10 CFR Part 71 with TS-R-1 and consistency with the DOT HMR is listed in the "Discussion" section of the *Federal Register* notice (FRN) within question C.

The Commission directed the staff, in Staff Requirements Memorandum (SRM) M031120A (NRC Agencywide Documents Access and Management System (ADAMS) Accession No. ML033240622), dated November 20, 2003 (Enclosure 4), to pursue an additional rulemaking with the DOT to remove an apparent double standard related to shipments of natural ores or naturally occurring radioactive material (NORM). This apparent double standard arises because the low-level material exemption that applies to natural materials and ores containing naturally occurring radionuclides depends on the intended use of the material.

In 1997, the NRC issued an emergency final rule (62 FR 5907; February 10, 1997) that revised the regulations on fissile material exemptions and the general licenses that apply to fissile material. Notwithstanding the final status of the rule, the NRC provided for a 30-day public comment period. The NRC subsequently published in the *Federal Register* (64 FR 57769; October 27, 1999) a response to the comments received on the emergency final rule and a request for information on any unintended economic impacts caused by the final rule. Based on the public comments on the emergency final rule, the NRC staff contracted Oak Ridge National Laboratory (ORNL) to review the fissile material exemptions and general license provisions, study the regulatory and technical bases associated with these regulations, and perform criticality model calculations for different mixtures of fissile materials and moderators. In its final rule (69 FR 3698; January 26, 2004) to make 10 CFR Part 71 compatible with the IAEA standards and make other transportation safety amendments, the NRC removed restrictions on the material that could qualify for the fissile material exemption in § 71.15(d). The fissile

material exemption in § 71.15(d) applies to uranium enriched in uranium-235 to a maximum of 1 percent by weight and with a total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235 (hereafter uranium enriched to a maximum of 1 percent). The restrictions removed in 2004 required that the material is distributed homogeneously throughout the package and does not form a lattice arrangement within the package. In the absence of special moderators, such low enriched uranium systems can only become critical if configured into a very large, heterogeneous, water-moderated lattice. Subsequent to removing the homogeneity requirement, the U.S. Department of Energy (DOE) contacted the NRC, indicating that DOE had a forthcoming shipment of slightly enriched uranium — just under 1 percent by weight — in the form of a large, heterogeneous lattice, which, if shipped, would have resulted in a lower margin of safety with respect to criticality than is typical for shipments using approved fissile material packages. This shipment was modified to reduce the amount of material per conveyance to a safely-subcritical mass.

DISCUSSION:

The proposed rulemaking would revise 10 CFR Part 71 to make the NRC regulations compatible with changes to the TS-R-1 and maintain consistency with changes in the DOT regulations; these revisions include changes to the exemption of low-level materials. In addition, the rulemaking would revise the fissile material exemption; make the regulation of QA programs more efficient; and make other changes to the requirements for the packaging and transportation of radioactive material, including a revision to the general license requirements.

In November 2012, IAEA issued new standards for the safe transport of radioactive material and designated them as “Specific Safety Requirements Number SSR-6” (SSR-6). This rulemaking does not incorporate the 2012 IAEA changes, which will undergo a comprehensive review by the NRC staff to determine if changes to 10 CFR Part 71 are warranted.

Exemption of Low-Level Materials

In 1996, radionuclide-specific exemption values replaced an activity-based exemption value (70 Bq/g) in the international transportation regulations. These radionuclide-specific activity concentration values were established in the IAEA Basic Safety Standards and later adopted in the international transportation regulations. The 1996 edition of the international transport regulations introduced the apparent double standard for natural materials and ores by excluding from regulation those natural material and ores that contain naturally-occurring radionuclides and are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the activity concentration values for exempt material. This natural material and ore was not typically regulated as radioactive material when the 70 Bq/g (0.002 $\mu\text{Ci/g}$) limit was used. The intent of setting the threshold at 10 times the activity concentration for this material is to avoid regulating the transportation of a large fraction of the large quantity of low-risk material that was not regulated with the 70 Bq/g (0.002 $\mu\text{Ci/g}$) activity-based exemption value, but which would be regulated if the radionuclide-specific exemption values were used.

The staff responded to the direction in SRM-M031120A by advocating for changes to be made in the IAEA’s transportation standards that would apply the 10-times exemption to all naturally

occurring radioactive materials regardless of their intended use. One such staff proposal resulted in the IAEA completing a Coordinated Research Program (CRP) on the appropriate level of regulatory control for the safe transport of NORM. The staff participated in this CRP. The recommendations of the CRP were addressed in the 2012 revision to the IAEA's transportation standards (SSR-6).

In the 2009 edition of the IAEA's transportation standards, the activity concentration for natural materials and ores containing naturally occurring radionuclides depends on the intended use of the material. Natural materials and ores that are not intended to be processed for the use of their radionuclides may have up to 10 times the activity concentration of natural materials and ores that are intended to be processed for use of their radioisotopes and still qualify for the low-level material exemption. This intended use clause was removed in the recently published 2012 edition of SSR-6. The proposed rule would change the exemption for natural materials and ores containing naturally occurring radionuclides to be consistent with the 2009 edition of the IAEA's transport regulations by allowing natural materials and ores that have been processed to qualify for the exemption.

Consistent with the direction in SRM-M031120A, the staff sought to include a proposal that would remove the apparent double standard for natural materials and ores for domestic transportation — where the intended use of the material determines whether the activity concentration, or 10-times the activity concentration, is used to determine the amount of regulatory oversight — and pursued this objective in its interactions with the DOT on this rulemaking. Removing the apparent double standard would require changes in the DOT regulations. This proposed rule does not include a proposed change to remove the apparent double standard, because the DOT did not include the change in its proposed rule. The IAEA adopted this change after the DOT published its proposed rule. Although the DOT may not remove the intended use clause in this rulemaking, this does not preclude making the change in a future rulemaking.

The staff plans to continue to work with the DOT to eliminate the disparate treatment of natural materials and ores that is based on their intended use in the domestic transportation regulations. Proposed changes that would be made to the regulation of natural materials and ores containing naturally occurring radionuclides are addressed in the "Discussion" section of the FRN within question D.

Fissile Material Exemption

The proposed rule would reinstate a restriction on the exemption from classifying uranium enriched in uranium-235 to a maximum of 1 percent as fissile material. Although the NRC had determined that the limits on restricted moderators were sufficient to assure subcriticality for all moderators of concern, the staff believes that additional restrictions are appropriate to increase the margin of safety with respect to criticality potential for shipments of material under the exemption for uranium enriched to a maximum of 1 percent at § 71.15(d). The limit on restricted moderators is considered to be sufficient to assure subcriticality for all moderators of concern and provides a measure of safety with respect to criticality potential for shipments of uranium enriched to a maximum of 1 percent. Therefore, the staff concluded that it is not necessary to publish an emergency final rule (bypassing the notice-and-comment process) as was done in the 1997 emergency final rule (62 FR 5907; February 10, 1997). Further, because the DOE is

likely to be the only shipper of such material, the staff has decided not to issue an Information Notice relating to this issue.

The proposed rule would require that the fissile material qualifying under the exemption at § 71.15(d) be distributed homogeneously and not form a lattice arrangement. This change would address the staff's concern that slightly enriched uranium distributed in a heterogeneous manner could be shipped with a smaller margin of safety with respect to criticality than is typically allowed for shipments using approved fissile material packages. The change would increase the minimum margin of safety with respect to criticality potential for fissile material shipped under the exemption and would make it comparable to that expected for shipments using approved fissile material packages. However, the change would further restrict the type of material that could qualify for the exemption. The more restrictive fissile material exemption for uranium enriched to a maximum of 1 percent would more likely apply to waste material from legacy operations than to fissile material in commercial use. Fissile material in commercial use is more likely to have higher enriched uranium distributed in a lattice arrangement during transport, which would not be affected by the proposed change. The proposed changes to the fissile material exemption are addressed in the "Discussion" section of the FRN within question M.

Quality Assurance

In 2004, the NRC was able to extend the duration of its QA program approvals from 5 to 10 years, because the periodic contact with the holders of the approval had become less important. Previously-issued renewals were not extended, so the renewals issued between December 2004 and November 2009 have not required renewal. Although the staff does not have experience with QA program approvals that have completed their 10-year approval period, the staff has observed that a longer duration of the QA program approval has not adversely affected the safety of nuclear material shipments. The staff's experience has been that the problems that arise are associated with the implementation of the QA program by the holder of the approval and are unrelated to the duration of the QA program approval. Therefore, the staff has concluded that it is appropriate to forego the staff's periodic review of the QA program descriptions and to issue approvals that would not expire. The staff believes that inspections of the holders of the QA program approval are more effective than reviews of the QA program approvals, which currently occur every 10 years, in ensuring the safe transportation of licensed material. The proposed changes would reduce the burden on both the NRC and the holders of the QA program approval. The proposed changes that would be made to the oversight of QA programs relating to transportation are addressed in the "Discussion" section of the FRN within questions H through K.

General License Changes

In applying the general license requirements, the staff has identified ambiguity in the general license provisions in §§ 71.17 and 71.21. The requirements to obtain a general license include (1) conditions which must be met to obtain a general license and (2) obligations and actions that are to be performed by the general licensee. The proposed changes would separate the issuance of the general license and the obligations of the general licensee. This would make it clear that a failure to comply with the obligations of the general license is a violation of the license conditions, but does not void the general license.

Only minor changes to Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material" (ADAMS Accession No. ML050540330), would be needed to address the proposed changes to the oversight of QA programs. Regulatory Guide 7.10 is currently scheduled to be updated by October 2012. In addition, the staff does not plan on providing any guidance on the fissile material exemption for uranium enriched to a maximum of 1 percent in § 71.15(d), aside from that provided in the enclosed FRN.

In summary, the proposed rule is consistent with the NRC strategic goal for safety and the associated strategic outcomes. This rulemaking would make changes that would maintain the consistency between the NRC regulations, TS-R-1, and the DOT HMR. By maintaining this consistency, the NRC would continue to ensure adequate protection of public health and safety, while also retaining the efficiency associated with consistent requirements. By re-introducing a requirement to limit the heterogeneity in low enriched material that may be transported under a general license, the NRC would be reducing the likelihood of inadvertent criticality events. The changes to the regulation of QA programs are being made to make the NRC oversight of the QA programs more efficient, allowing resources to be redirected towards activities that provide a greater contribution towards reducing the risk of transportation incidents.

AGREEMENT STATE ISSUES:

The staff provided a copy of the draft proposed rule FRN to the Agreement States on April 6, 2012, so they could have an early opportunity for review. Comments were received from the States of Arkansas and Washington. The State of Arkansas commented on the information provided for the address of the American National Standards Institute used for the incorporation by reference of the International Organization for Standardization standards in § 71.70. The address has been updated in Enclosure 1. The State of Washington provided several comments. One comment asked the NRC to clarify how the general license changes would affect prior notifications of shipments. Another comment expressed concern that the proposed changes would require the release of protected information during a shipment. The staff changed the Statements of Consideration to clarify that the proposed amendments do not change the current notification process and do not affect the required timing or content of the current requirements relating to the prior use of a package or, where required, the prior notification of shipments. Another comment, in response to the proposed changes for general licenses for previously approved packages, expressed support for grandfathering. The grandfathering provision that was in § 71.19(a) has already expired and has already been removed from the CFR. The decision to have this grandfathering provision expire was discussed extensively in the Statements of Consideration to the 2004 final rule (January 26, 2004; 69 FR 3698). The State of Washington also provided a comment on the anticipated time allowed for the rule to become effective, but did not express concerns with the proposed amount of time or propose a different amount of time.

The staff has analyzed the proposed 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 proposed changes include program elements that are classified as Compatibility Category "NRC" and program elements that are a matter of compatibility with the Agreement States and are assigned Compatibility Categories "B," "C," and "D."

The Standing Committee on Compatibility reviewed the proposed rule and agreed that these amendments to the NRC regulations are a matter of compatibility between the NRC and the Agreement States and agreed with the Compatibility Categories assigned in the Compatibility Table in the Statements of Consideration to the proposed rule. Neither State commenting on the draft proposed rule commented on the Compatibility Categories assigned in the Compatibility Table.

COMMITMENTS:

The staff will coordinate with DOT staff on the publication of the final rule and its effective date. The coordination will include the concurrent publication of the NRC and DOT final rules in the *Federal Register* and the effective dates for the requirements in the final rule.

The staff will continue to work with the DOT to eliminate the disparate treatment of natural materials and ores that is based on their intended use in the domestic transportation regulations.

The staff will make the draft revision to Regulatory Guide 7.10 publicly available for comment concurrent with the publication of the proposed rule.

The staff will review the 2012 edition of SSR-6 to determine if changes to 10 CFR Part 71 are warranted in a future rulemaking.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to 10 CFR Part 71 (Enclosure 1).

Note:

- a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
- 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 draft Regulatory Analysis has been prepared for this rulemaking (Enclosure 2).
- d. That a draft Environmental Assessment has been prepared for this rulemaking (Enclosure 3).
- e. That appropriate Congressional committees will be informed of this action.

- f. 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.
- g. That Office of Management and Budget (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.

RESOURCES:

The funding for this rulemaking is provided by both the Spent Fuel Storage and Transportation and Corporate Support Business Lines. To complete and implement the rulemaking, 2.1 full-time equivalent (FTE) positions will be required. The FY 2013 President's budget includes 1.4 FTE and 0.7 FTE is requested in the FY 2014 Planning, Budgeting, and Performance Management process.

SCHEDULE:

To maintain consistency in the NRC and the DOT regulations, the effective date of the final rule provisions that are common to the DOT should have the same effective date. Concurrent publication of the final rules helps to maintain consistency in the NRC and the DOT regulations. The parallel NRC and DOT rulemakings are intended to be consistent for those areas that are common to the two sets of regulations. At this time, the DOT has not ruled out publishing its final rule concurrent with the NRC's final rule, planned for March 2014, but is considering publishing their final rule as early as summer 2013.

COORDINATION:

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

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. *Federal Register* notice
2. Draft Regulatory Analysis
3. Draft Environmental Assessment
4. SRM-M031120A

- f. 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.
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1. *Federal Register* notice
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