

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

February 15, 2013

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0166

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 15, 2013.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

1). Bater

Andrew L. Bates Acting Secretary of the Commission

Attachments:

- 1. Voting Summary
- 2. Commissioner Vote Sheets
- cc: Chairman Macfarlane Commissioner Svinicki Commissioner Apostolakis Commissioner Magwood Commissioner Ostendorff OGC EDO PDR

VOTING SUMMARY - SECY-12-0166

RECORDED VOTES

	APRVD DISAPRVD ABSTAIN	NOT PARTICIP COMMENTS	DATE
CHRM. MACFARLANE	x	Х	1/28/13
COMR. SVINICKI	x	Х	2/11/13
COMR. APOSTOLAKIS	x	X	1/30/13
COMR. MAGWOOD	x	Х	2/1/13
COMR. OSTENDORFF	Х	x	2/1/13

.

NOTATION VOTE

RESPONSE SHEET

- TO: Annette Vietti-Cook, Secretary
- FROM: Chairman Allison M. Macfarlane

SUBJECT: SECY-12-0166 – PROPOSED RULE: REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION REQUIREMENTS (RIN 3150-AI11)

Approved X Disapproved Abstain

Not Participating _____

COMMENTS: Below <u>Attached X</u> None <u></u>

1/28 13

Entered on "STARS" Yes X No

Chairman Macfarlane's Comments on SECY-12-0166, "Proposed Rule: Revisions to the Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements (RIN 3150-Al11)"

I approve the publication of the draft rulemaking for public comment.

I commend the staff in coordinating with the Department of Transportation (DOT) in maintaining consistent transportation standards in the United States, and with our international counterparts in maintaining global transportation standards.

The staff should continue to work with DOT to eliminate the noted differences in the exemption of low-level materials for natural materials and ores. At the time of providing the final rule for approval, the staff should update the Commission on its efforts with DOT on this issue. The staff should clarify the plan(s) to update the rule in the future, including consideration of any future IAEA compatibility updates.

The staff should also include the following edit to the Draft Federal Register Notice:

Page 7, 1st paragraph, first sentence:

The IAEA was formed by member nations to promote safe, secure, and peaceful nuclear technologies. It is authorized to establishes safety standards to protect public health and safety and to minimize the danger to life and property.

Macfarlane

NOTATION VOTE

RESPONSE SHEET

- TO: Annette Vietti-Cook, Secretary
- FROM: COMMISSIONER SVINICKI
- SUBJECT: SECY-12-0166 PROPOSED RULE: REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION REQUIREMENTS (RIN 3150-AI11)

Approved XX Disapproved Abstain

Not Participating _____

COMMENTS: Below XX Attached XX None ____

I approve for publication, in the *Federal Register*, the proposed amendments to 10 CFR Part 71 (Enclosure 1 to SECY-12-0166), subject to the attached edits. The staff should make the draft revision to Regulatory Guide 7.10 publicly available for comment concurrent with the publication of the proposed rule. The staff should continue to work with the U.S. Department of Transportation to eliminate the disparate treatment of natural materials and ores that is based on their intended use in the domestic transportation regulations. I also approve the edits to the draft notification letters proposed by Commissioner Apostolakis in his vote.

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SIGNATURE		

02/ /13 DATE

Entered on "STARS" Yes 📈 No ____

shipping of fissile material under a general license. The parallel DOT proposed rulemaking was published in the *Federal Register* on August 12, 2011 (76 FR 50332).

DATES: Submit comments by [INSERT DATE: 75 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments specific to the information collections aspect of this rule by [INSERT DATE: 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received after thisthese dates will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before thseis dates.

ADDRESSES: You may access information and comment submissions related to this proposed rule, which the NRC possesses and are publicly available, by searching on http://www.regulations.gov under Docket ID NRC-2008-0198. You may submit comments related to this proposed rule by any of the following methods:

• Federal rulemaking Web site: Go to <u>http://www.regulations.gov</u> and search for Docket ID NRC-2008-0198. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: <u>Carol.Gallagher@nrc.gov</u>.

• E-mail comments to: <u>Rulemaking.Comments@nrc.gov</u>. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.

• Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

 Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

• Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

regulations. In addition, the NRC is making other revisions to its transportation regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) part 71. These other revisions include NRC-initiated changes that would affect administrative procedures for the quality assurance program requirements described in 10 CFR part 71, subpart H; re-establish restrictions on material that qualifies for the fissile material exemption; clarify the requirements for a general license; clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and make other editorial changes.

Compatibility with IAEA and Consistency with DOT Transportation Regulations

The IAEA is authorized to establishes safety standards to protect public health and safety and to minimize the danger to life and property. The IAEA has developed international safety standards for the safe transport of radioactive material, "Regulations for the Safe Transport of Radioactive Material" (2009) (referred to as TS-R-1). The IAEA safety standards and regulations are developed in consultation with the competent authorities of Member States, so they reflect an international consensus on what is needed to provide for a high-level of safety. By providing a global framework for the consistent regulation of the transport of radioactive material, TS-R-1 facilitates international commerce and contributes to the safe conduct of international trade involving that material. By periodically revising its regulations to be compatible with IAEA and DOT regulations, the NRC is able to remove inconsistencies that could impede international commerce and reflect knowledge gained in scientific and technical advances and accumulated experience.

On January 26, 2004 (69 FR 3698), the NRC published in the *Federal Register* a final revision to 10 CFR part 71, "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments." That revision, in combination with a parallel revision of the DOT hazardous materials transportation regulations, brought the United States

revisions to TS-R-1. Subsequent to the 1996 edition of TS-R-1 (as amended in 2000), the IAEA published revisions to TS-R-1 in 2003, 2005, and 2009.

This rulemaking effort involves harmonizing the NRC regulations at 10 CFR part 71 with changes to the IAEA transportation regulations through "Regulation for the Safe Transport of Radioactive Material, 2009 Edition," No. TS-R-1. Copies of TS-R-1 may be obtained from the United States distributors, Bernan, 15200 NBN Way, P.O. Box 191, Blue Ridge Summit, PA 17214; telephone: 1-800-865-3457; e-mail: customercare@bernan.com, or Renouf Publishing Company Ltd., 812 Proctor Ave., Ogdensburg, NY 13669-2205; telephone: 1-888-551-7470; e-mail: orders@renoufbooks.com. An electronic copy may be found at the following IAEA Web site: <u>http://www-pub.iaea.org/MTCD/publications/PDF/Pub1384</u> web.pdf. The regulations in TS-R-1 represent an accepted set of requirements that are considered to provide a high level of safety in the packaging and transportation of radioactive materials and provide a basis and framework that facilitates the development of internationally-consistent regulations. Internationally-consistent regulations for the transportation and packaging of radioactive material reduce impediments to trade; facilitate international cooperation; and, when the regulations provide a high level of safety, can reduce risks associated with the import and export of radioactive material. Harmonization represents the effort to increase the consistency or compatibility between national regulations and the internationally-accepted requirements, within the constraints of an existing national legal and regulatory framework.

In November 2012, the 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 changes, which will undergo a comprehensive review by the NRC staff to determine if additional changes to 10 CFR part 71 are warranted.

Historically, the NRC has coordinated its revisions to 10 CFR part 71 with the DOT, because the DOT is the U.S. competent authority for transportation of hazardous materials.

B. Who is Affected by this Action?

This action would affect NRC licensees authorized by a specific or general license issued by the Commission 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; holders of, and applicants for, a CoC; and holders of a <u>10 CFR part 71</u>, <u>Subpart H</u> quality assurance program approval. <u>This action would also affect holders of quality assurance program</u> <u>approvals under Appendix B of part 50 or subpart G of part 72 to the extent that those approvals</u> <u>apply to transport packaging as specified in 10 CFR 71.101(f)</u>, "*Previously approved programs.*" This action would change requirements that are matters of compatibility. Agreement States would be required to update their regulations and Agreement State licensees would be affected by the changes to the Agreement State regulations.

C. <u>Which Changes are Being Made to Increase the Compatibility with the International</u> Atomic Energy Agency Regulations (TS-R-1) and Consistency with DOT Regulations?

The NRC has identified changes in 10 CFR part 71 that would make the NRC regulations more consistent or compatible with the international transportation regulations. These changes would also improve the consistency with the current DOT regulations or would maintain consistency between 10 CFR part 71 and DOT regulations by making changes that correspond to those proposed by the DOT. The NRC is proposing the following changes to 10 CFR part 71.

1. In the 2003 Edition of TS-R-1, the IAEA changed the scope of TS-R-1 as it applies to natural materials and ores by adding language that addresses the processing of these materials (paragraph 107(e) of the 2009 edition of TS-R-1). The NRC is proposing to include the concept

which addresses non-radioactive solid objects with radioactive substances present on any surface in quantities not in excess of certain levels. In conjunction with this proposed change, a definition of "contamination" corresponding to the definition in TS-R-1 would be added to § 71.4.

3. The NRC is proposing to amend the following definitions in 10 CFR 71.4 to reflect the current definitions in TS-R-1: "Criticality Safety Index (CSI)"; "Low Specific Activity (LSA) material"; and "uranium — natural, depleted, enriched". When the NRC last revised the definition for LSA material, the NRC added the modifier "not," which resulted in the NRC definition becoming inconsistent with the DOT and IAEA definitions. The NRC is proposing to correct this, so that LSA material includes material intended to be processed for its radionuclides.

4. The NRC is proposing to adopt the use of the Class 5 impact test prescribed in the International Organization for Standardization (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 was less than 500 grams.

5. The NRC is proposing to incorporate by reference International Organization for StandardizationISO document 2919, "Radiation protection — Sealed radioactive sources — General requirements and classification," Second Edition (February 15, 1999), ISO 2919:1999(E), and International Organization for StandardizationISO document 9978, "Radiation protection — Sealed radioactive sources — Leakage test methods," First Edition (February 15, 1992), ISO 9978:1992(E).

 The NRC is proposing to change the description of billet used in the percussion test in § 71.75(b)(2)(ii) by replacing "edges" with "edge."

7. The NRC is revising the definition of special form radioactive material in § 71.4 to allow special form radioactive material that is successfully tested in accordance with the current

requirements to continue to be transported as special form radioactive material, if the testing was completed before the effective date of the final rule.

8. In appendix A, Table A-1, the NRC is proposing to eliminate the A_1 and A_2 values for californium-252 (Cf-252) for domestic use. The A_1 and A_2 values for californium-252 would be consistent with the IAEA values.

9. The NRC is proposing to include krypton-79 (Kr-79) in Table A-1 and Table A-2. The A₁ and A₂ values in Table A-1 and the activity concentration for exempt material and the activity limit for exempt consignment would be consistent with the IAEA values in the 2009 edition of TS-R-1.

10. The NRC is proposing to revise footnote a to Table A-1, "A₁ and A₂ values for radionuclides" to include the list of parent radionuclides whose A₁ and A₂ values include contributions from daughter radionuclides with half-lives of less than 10 days in footnote a to Table 2, "Basic <u>FR</u>adionuclide <u>V</u>alues," in TS-R-1 (2009 edition), with the exception of argon-42 (Ar-42) and tellurium-118 (Te-118), which appear in footnote a to Table 2 in TS-R-1 (2009 edition), but do not appear within Table 2.

11. The NRC is proposing to move and revise footnote c to Table A-1 to make clear that only for iridium-192 (Ir-192) in special form is it appropriate for the activity of Ir-192 to be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance.

12. In appendix A, Table A-2, Tthe NRC is proposing to revise the activity limit for exempt consignment for tellurium-121m (Te-121m) to be consistent with the new IAEA value.

13. The NRC is proposing to revise the list of parent radionuclides and their progeny included in secular equilibrium in footnote b to Table A-2, "Exempt material activity concentrations and exempt consignment activity limits for radionuclides," to be consistent with the list accompanying Table 2, "Basic fR adionuclide \sqrt{V} alues," in TS-R-1 (2009 edition).

14. The NRC is proposing to revise the descriptive phrases for different categories of unknown radionuclides and mixtures in Table A-3 to be consistent with the IAEA descriptions in <u>Table 3, "Basic Radionuclide Values for Unknown Radio Nuclides or Mixtures," in TS-R-1 (2009</u> edition). The descriptive phrases for "Only alpha emitting nuclides are known to be present" and "No relevant data are available" would be revised.

D. How is the NRC Changing the Exemption for Materials with Low Activity Levels?

The NRC is proposing to revise its exemption for natural materials and ores containing naturally occurring radionuclides to reflect changes in the scope of TS-R-1. In its proposed rule (76 FR 50332; August 12, 2011), the DOT proposed adopting these changes.

The TS-R-1 includes statements that describe its scope. First, there is a description of activities included within the scope of regulation. Second, TS-R-1 has a list of material to which TS-R-1 does not apply, hereafter referred to as "non-TS-R-1 material." Included in the list of non-TS-R-1 material are natural materials and ores containing naturally occurring radionuclides. These natural materials and ores are not intended to be processed for their radionuclides, provided that the activity concentration for the material does not exceed 10 times the activity concentration for the material does not exceed 10 times the activity materials and ores containing naturally occurring radionuclides. These natural material. In the 2003 edition of TS-R-1, the description of natural materials and ores containing naturally occurring radionuclides contained in the list of non-TS-R-1 material was revised to add natural materials and ores that have been processed.

In the 2003 edition of TS-R-1, "non-radioactive solid objects with radioactive substances on any surfaces" in quantities not exceeding certain values were identified as being outside of the scope of the transportation regulations.

The NRC has established an exemption at 10 CFR 71.14 that exempts licensees from the requirements of 10 CFR part 71 for certain natural materials and ores. The exemption for low-level materials exempts licensees from the requirements of 10 CFR part 71 with respect to the shipment or carriage of material that qualifies for the exemption and they would be allowed to transport natural material or ore that qualifies for the exemption without the material being regulated as a hazardous material during transportation; however, all other NRC regulations that apply to this material would continue to apply. The exemption at § 71.14(a)(1) is consistent with the 1996 edition of TS-R-1 (as amended in 2000) and 49 CFR 173.401(b), as they apply to natural materials and ores containing naturally occurring radionuclides. The NRC is proposing to update this exemption to include the shipment of natural materials and ores containing naturally occurring radionuclides that have been processed, which would retain consistency with DOT regulations and harmonize the NRC regulations with the 2009 edition of TS-R-1. This exemption would continue to be limited to those natural materials and ores containing naturally occurring radionuclides whose activity concentrations may be up to 10 times the activity concentration specified in Table A-2, in appendix A to 10 CFR part 71.

The NRC is proposing to correct the definition of LSA-I material, so that it applies to uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides which that are intended to be processed for their radionuclides. The low-level material exemption at § 71.14(b)(3), which includes packages containing only LSA material, would now apply to LSA-I material (i.e., material intended to be processed for its radionuclides).

Natural material and ore containing naturally occurring radionuclides that are not intended to be processed for these radionuclides could qualify for the low-level material exemption at 10 CFR 71.14(a)(1). With the correction to the definition of LSA-I material, uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides which-that are intended to be processed for these radionuclides may be able to qualify for the low-level material exemption at § 71.14(b)(3), provided that the other restrictions are satisfied. The restrictions include: 1) the package

Description not Necessary?," the NRC would re-issue NRC Form 311 without an expiration date. The 24-month period for reporting of changes is proposed to begin on the date of the NRC approval of a quality assurance program issued with no expiration date, as specified by the date of signature at the bottom of NRC Form 311, "Quality Assurance Program Approval for Radioactive Material Packages."

As discussed under question P, "What Should I Consider as I Prepare My Comments to the NRC?," the NRC is proposing to require quality assurance program approval holders to submit a report every 2 years that describes the changes that were made to their quality assurance program description that do not reduce a commitment in the quality assurance program description approved by the NRC. The NRC is seeking to balance the regulatory burden for submitting this information with the NRC need to ensure that the NRC has current information for its regulatory oversight of quality assurance program approval holders, which would include using the information for inspections. The NRC is requesting comment on the following issue: would a different frequency be more appropriate for reporting changes to an approved quality assurance programs that do not reduce a commitment in a quality assurance program description approved by the NRC would be more appropriate?

K. <u>How do the Requirements in Subpart H, "Quality Assurance," Change with the Removal</u> of the Footnote in 10 CFR 71.103?

The NRC is proposing to remove the footnote in § 71.103 regarding the use of the term "licensee" in subpart H, because it is no longer necessary. The removal of the footnote does not change the quality assurance requirements in subpart H. The footnote regarding use of the term "licensee" was included to clarify that the quality assurance requirements in subpart H the quality assurance program description approved by the NRC. The NRC is seeking to balance the regulatory burden for submitting this information with the NRC need to ensure that the NRC has current information for its regulatory oversight of quality assurance program approval holders, which includes using the information for inspections. Inspections of certificate holders occur approximately every 3 years and inspections of licensees who use packages occur on an as-needed basis. The NRC is requesting comment on whether a different frequency would be more appropriate for reporting changes to an approved quality assurance program that do not reduce a commitment in a quality assurance program description approved by the NRC_-would be more appropriate?

b. In § 71.15(d), the NRC is proposing to reintroduce restrictions on low-enriched fissile material — uranium enriched in U-235 to a maximum of 1 percent by weight, and with a total plutonium and U-233 content of up to 1 percent of the mass of uranium-235 — by requiring that it be distributed homogeneously and not form a lattice arrangement. The NRC is seeking comment on the clarity of this requirement for implementation.

c. The CER describe the challenges that licensees, certificate holders, States, or other entities may encounter when implementing the new regulatory requirements (e.g., rules, generic letters, orders, backfits, inspections). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new or complex regulatory actions, within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). The CER can potentially distract licensee or other entity staff from executing other primary duties that ensure safety or security. The NRC is specifically requesting comment on the cumulative effects of this rulemaking. In developing comments on the CER, consider the following questions:

i. In light of any current or projected CER challenges, does the proposed rule's

The definition of "Low Specific Activity (LSA) material" would be revised to be more consistent with the definition in DOT regulations at 49 CFR 173 and TS-R-1 by revising paragraphs (1)(i) and (1)(ii). In paragraph (1)(i), the definition is changed to make the description of LSA-I material apply to material which-that is intended to be processed for the use of the uranium, thorium, and other naturally occurring radionuclides.

The definition of "special form radioactive material" would be revised to allow special form radioactive material that was successfully tested using the current requirements of § 71.75(d) to continue to qualify as special form material, if the testing was completed before the date of the final rule. The reference to the version of 10 CFR part 71 in effect on March 31, 1996, would be corrected by changing 1983 to 1996.

The definition of "uranium — natural, depleted, enriched" would be revised by adding "(which may be chemically separated)" to paragraph (1), which applies to natural uranium.

Section 71.6 Information collection requirements: OMB approval.

Section 71.106 is added to the list of sections with information collections.

Section 71.14 Exemption for low-level materials.

Paragraph 71.14(a)(1) would be revised to allow natural material and ores that contain naturally occurring radionuclides and that have been processed for purposes other than the extraction of the radionuclides to qualify for the exemption. Natural material or ore that has been processed, but has not been incorporated into a manufactured product, such as an article, instrument, component of a manufactured article or instrument, or consumer item could qualify for the exemption. Slags, sludges, tailings, residues, bag house dust, oil scale, and washed sands that are the byproducts of processing or refining would be considered as a natural material and could qualify for the exemption, provided that they were not incorporated into a

manufactured product. To qualify for this exemption, the activity concentration of the natural material or ore could not exceed 10 times the activity concentration values and the material is not intended to be processed for the use of the radionuclides.

A reference to Table A-3 in appendix A would be added as a source of activity concentration values that may be used to determine whether natural material or ore would qualify for the exemption. Table A-3 would provide activity concentration values for exempt material that would be used for individual radionuclides whose identities are known, but which are not listed in Table A-2.

Paragraph 71.14(a)(3) would be added to provide an exemption for non-radioactive solid objects which that have radioactive substances present on the surfaces of the object, provided that the quantity of radioactive substances is below the quantity used to define contamination. The definition of "contamination" would be added to § 71.4.

Section 71.15 Exemption from classification as fissile material.

Paragraph 71.15(d), which applies to fissile material in the form of uranium enriched in U-235 to a maximum of 1 percent by weight, would be revised. The fissile material would be required to be distributed homogeneously and not form a lattice arrangement, where concentrated fissile material is separated by non-fissile material in a regular, repeating pattern.

Section 71.17 General license: NRC-approved package.

Paragraph 71.17(c) would be revised to clarify that the general licensee must comply with the requirements in § 71.17(c)(1) through (c)(3).

Section 71.19 Previously approved package.

Paragraphs 71.19(b) through (e) would be redesignated as §§ 71.19(a) through (d).

Appendix A Determination of A₁ and A₂.

In paragraphs IV.a. through IV.f., the equations and accompanying text would be revised to make minor corrections to the equations and the accompanying text. In paragraphs IV.a. and IV.b., the description of the equations would make it explicit that B(i) is the activity of radionuclide i in special form and normal form in paragraphs IV.a. and IV.b., respectively.

Paragraph IV.c. would be added and paragraphs IV.c. through IV.f. would be redesignated as paragraphs IV.d. through IV.g., respectively. Paragraph IV.c. would provide an equation to be used for determining the quantity of radioactive material that can be shipped in a package that contains both special form and normal form radioactive material. This equation would increase the consistency between appendix A and TS-R-1.

In paragraph V., the existing text would be redesignated as paragraph V.a. Paragraph V.b. would be added to provide direction on calculating the exempt activity concentration for a mixture and the exempt consignment activity limit of a mixture, when the identity of each radionuclide is known, but the individual activities of some radionuclides are not known.

Table A-1 would be revised to change the A₁ value for Cf-252 from 5.0x10⁻² TBq to 1.0x10⁻¹ TBq, and from 1.4 Ci to 2.7 Ci. Footnote h would be deleted and the following corresponding changes would be made: 1) the reference to footnote h would be removed from Cf-252, 2) the entry for molybdenum-99 (Mo-99) would be revised to identify footnote h instead of footnote i, and 3) footnote i would be redesignated as footnote h. Footnote c in the entry for Ir-192 would be moved, so that it is clear that it applies only to iridium in special form. Footnote c would also be revised to specifically state that the activity of iridium in special form may be determined through measurement at a prescribed distance from the source. Table A-1 would be revised to include values for Kr-79. The A₁ and A₂ values for Kr-79 correspond to the A₁ and A₂ values in TS-R-1 (2009 edition) and the specific activity would be 4.2x10⁴ TBq/g

ML12187A109) that this proposed rule, if adopted, would not be a major federal action significantly affecting the quality of the human environment.

Many of the proposed changes fall under a categorical exclusion for which the Commission has previously determined that such actions, neither individually nor cumulatively, would have significant impacts on the human environment. The categorical exclusions in 10 CFR 51.22(c)(2) and 10 CFR 51.22(c)(3) were used in the Environmental Assessment. The categorical exclusion at 10 CFR 51.22(c)(2) applies to amendments to 10 CFR part 71 that are corrective or of a minor or non-policy nature and do not substantially modify the regulations. The categorical exclusion at 10 CFR 51.22(c)(3) applies to amendments to 10 CFR part 71 which that relate to: (i) procedures for filing and reviewing applications for licenses or construction permit or early site permit or other forms of permission or for amendments to or renewals of licenses or construction permits or early site permits or other forms of permission; (ii) recordkeeping requirements; (iii) reporting requirements; (iv) education, training, experience, qualification, or other employment suitability requirements; or (v) actions on petitions for rulemaking relating to these amendments.

Those changes not qualifying for a categorical exclusion were evaluated for their environmental impacts and include changes to: 1) definitions; 2) the exemption of low-level materials; 3) the fissile material exemption for low-enriched fissile material; 4) alternate tests that may be used for the qualification of special form material; 5) preliminary determinations; 6) the A_1 and A_2 values for radionuclides; and 7) the exempt material activity concentrations and exempt consignment activity limits for radionuclides. The effects of these changes are addressed in more detail in the Environmental Assessment. The changes to the fissile material exemption would further reduce the potential for criticality during the transport of low-enriched fissile material under the fissile material exemption. Other changes, such as those relating to the exemption of low-level material, the A_1 and A_2 values for radionuclides, and the exempt

- Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.
- (2) Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport.

* * * * *

Criticality Safety Index (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in §§ 71.22, 71.23, and 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

* * * * *

Low Specific Activity (LSA) material means radioactive material with limited specific activity, which is nonfissile or is excepted under § 71.15, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

(1) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides which-that are intended to be processed for the use of these radionuclides;

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements which-that apply to design, fabrication, testing, and modification of packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements which-that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

* * * *

(c) * * *

(2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each certificate holder, or applicant for a CoC shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.

* * * * *

17. In § 71.103, paragraph (a) is revised to read as follows:

§ 71.103 Quality assurance organization.

(a) The licensee, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include

(1) The use of a quality assurance standard approved by the NRC which that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(c) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

Section 71.135 is revised to read as follows:

§ 71.135 Quality assurance records.

The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by § 71.106, the instructions, procedures, and drawings

required by § 71.111 to prescribe quality assurance activities and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee certificate holder and applicant for a CoC shall retain the superseded material for 3 years after it is superseded.

20. In appendix A to part 71, IV.a., and IV.b. are revised, paragraphs IV.c. through IV.f. are redesignated as paragraphs IV.d. through IV.g. and are revised, paragraph IV.c. is added, paragraph V. is redesignated as paragraph V.a., and paragraph V.b. is added before Table A-1 to read as follows:

APPENDIX A TO PART 71 - DETERMINATION OF A1 AND A2

* * * *

IV. * * *

a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_{i} \frac{B(i)}{A_{i}(i)} \le 1$$

where B(i) is the activity of radionuclide i in special form, and $A_1(i)$ is the A_1 value for radionuclide i.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_{i} \frac{B(i)}{A_2(i)} \le 1$$

where B(i) is the activity of radionuclide i in normal form, and $A_2(i)$ is the A_2 value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity which<u>that</u> may be transported in a Type A package is as follows:

$$\sum_{i} \frac{\mathbf{B}(i)}{\mathbf{A}_{i}(i)} + \sum_{j} \frac{C(j)}{A_{2}(j)} \le 1$$

Where B(i) is the activity of radionuclide i as special form radioactive material, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

d. Alternatively, the A₁ value for mixtures of special form material may be determined as follows:

A₁ for mixture =
$$\frac{1}{\sum_{i} \frac{f(i)}{A_{i}(i)}}$$

NOTATION VOTE

RESPONSE SHEET

10:	Annette Vietti-Cook, Secretary			
FROM:	Commissioner Apostolakis			
SUBJECT:	SECY-12-0166 – PROPOSED RULE: REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION REQUIREMENTS (RIN 3150-AI11)			
Approved X	Disapproved Abstain			
Not Participating				
COMMENTS:	Below X Attached None			

I approve staff recommendation subject to the edits noted below.

Revise the congressional letters as follows:

"The U.S. Nuclear Regulatory Commission (NRC) intends to publish a proposed rule in the Federal Register that would amend part 71 of Title 10 of the Code of Federal Regulations, "Packaging and Transportation of Radioactive Material." These amendments, developed in consultation with the U.S. Department of Transportation (DOT), would harmonizemake the NRC regulations compatible with the recent revisions to the International Atomic Energy Agency regulations standards for the safe transport of radioactive material, and would maintain consistency with DOT regulations., and make other changes. The proposed changes are necessary to maintain a consistent regulatory framework for the transportation and packaging of radioactive material. - The proposed amendments would also make the regulation of guality assurance programs more efficient by allowing those changes that do not reduce the commitments that the guality assurance approval holder has made to the NRC to be implemented without having to obtain the prior approval of the NRC and extending the duration of quality assurance program approvals. These proposed amendments would also and further clarify the responsibilities of general licensees and would increase the margin of safety for shipping uranium enriched in uranium 235 to a maximum of 1 percent by weight under a general license."

SIGNATURE

1/39/12

Entered on "STARS" Yes 🗹 No

NOTATION VOTE

RESPONSE SHEET

- Annette Vietti-Cook, Secretary TO:
- FROM: **COMMISSIONER MAGWOOD**

SUBJECT: SECY-12-0166 – PROPOSED RULE: REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC **ENERGY AGENCY TRANSPORTATION REQUIREMENTS (RIN 3150-AI11)**

Approved	Disapproved	Abstain
Not Participating		

COMMENTS: Below Attached X None

SIGNATU

1 February 2013

DATE

Entered on "STARS" Yes X No

Commissioner Magwood's Comment on SECY-12-0166 – "Proposed Rule: Revisions to Transportation Safety Requirements and Harmonization with <u>International Atomic Energy Agency Transportation Requirements"</u>

I approve issuance of the proposed rule to amend 10 CFR Part 71 to make the NRC's 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. I appreciate the staff's hard work with the DOT to develop this rule. It is essential that we have coherent and effective transportation regulation both domestically and internationally.

I agree with the Chairman that the staff should continue to work with DOT to eliminate the noted differences in the exemption of low-level materials for natural materials and ores. I also agree that the staff should keep the Commission informed regarding efforts with DOT on this issue.

2/1/13

William D. Magwood, IV Date

NOTATION VOTE

RESPONSE SHEET

- Annette Vietti-Cook, Secretary TO:
- FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0166 – PROPOSED RULE: REVISIONS TO TRANSPORTATION SAFETY REQUIREMENTS AND HARMONIZATION WITH INTERNATIONAL ATOMIC ENERGY AGENCY TRANSPORTATION **REQUIREMENTS (RIN 3150-AI11)**

Approved X Disapproved Abstain

Not Participating _____

COMMENTS: Below ____ Attached ____ None _X___

SIGNATURE

2/1/13 DATE

Entered on "STARS" Yes X No