



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

April 14, 2015

SECRETARY

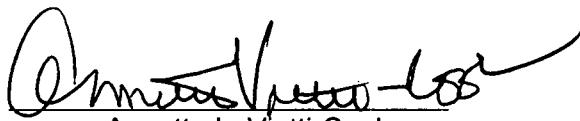
COMMISSION VOTING RECORD

DECISION ITEM: SECY-14-0100

TITLE: FINAL 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 April 14, 2015.

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



Annette L. Vietti-Cook
Secretary of the Commission

Enclosures:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
OGC
EDO
PDR

VOTING SUMMARY - SECY-14-0100

RECORDED VOTES

		NOT APRVD	DISAPRVD	ABSTAIN	PARTICIP	COMMENTS	DATE
CHRM. BURNS	X				X		2/28/15
COMR. SVINICKI	X				X		3/30/15
COMR. OSTENDORFF	X				X		10/30/14
COMR. BARAN	X				X		3/18/15

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Burns

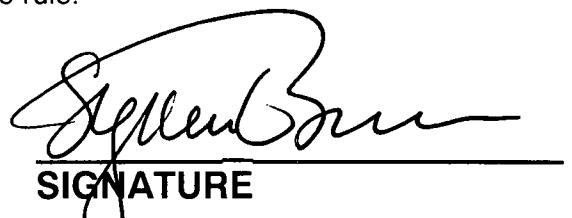
SUBJECT: SECY-14-0100: Final Rule: Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements (RIN 3150-Ai11)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below X Attached X None _____

I approve the staff's recommendation to publish the final rule in the Federal Register, subject to the attached edits to the Federal Register notice and Congressional letters, and I support staff's determination that this final rule, if adopted, will not have significant impact on a substantial number of small entities. Additionally, several licensing and inspection guidance documents will need to be revised to reflect this regulatory change and should be available for NRC staff and licensee use shortly after publication of the rule.



Chairman Burns
SIGNATURE

28 February 2015
DATE

Entered on "STARS" Yes ✓ No _____

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These IAEA safety standards and regulations were developed in consultation with IAEA Member States, and 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 radioactive 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.

This rulemaking harmonizes the NRC's regulations with the IAEA's transportation regulations in TS-R-1 and aligns with the DOT regulations. The regulations in TS-R-1 represent an accepted set of requirements that provide a high level of safety in the packaging and transportation of radioactive materials and provides for 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.

In November 2012, the IAEA issued revised standards for the safe transport of radioactive material and designated them as "Specific Safety Requirements Number SSR-6" (SSR-6). The present NRC rulemaking does not incorporate the SSR-6 requirements, because

references the quality assurance programs for industrial radiographers is updated by changing § 71.12(b) to § 71.17(b).

XV. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC uses the consensus standards identified as follows and will incorporate them by reference. The NRC is adopting ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), for the Class 4 and Class 5 impact tests and the Class 6 temperature test; and ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), for the leaktightness tests.

In other portions of this final rule, the NRC is revising requirements that do not constitute the establishment of a standard that establishes generally applicable requirements. These revisions to the NRC's requirements include changes to: 1) the scope of material falling under an existing exemption for natural materials and ores containing naturally occurring radionuclides at an activity concentration below a specified value, 2) conditions on general licenses, 3) the oversight of quality assurance programs, and 4) the removal of transitional arrangements for previously approved packages.

The Honorable **Barbara Boxer**
Chairman, Committee on Environment
and Public Works
United States Senate
Washington, DC 20510

Comment [SGB1]: Revise all the letters to reflect the 114th Congress.

Dear Madam Chairman:

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to the packaging and transportation of radioactive material. Some of the amendments have been made in consultation with the U.S. Department of Transportation (DOT), where the NRC is conforming its regulations to maintain consistency with the International Atomic Energy Agency's regulations regarding the international transportation of radioactive material. The DOT likewise amended its regulations in July 2014. The NRC final rule will soon be published in the *Federal Register*. The NRC's conforming amendments will become effective on July 13, 2015, which is the same date that the for mandatory compliance with DOT amendments become effective. For more information, see the NRC's enclosed final rule.

Please feel free to contact me at (301) 415-1776 if you have questions or need more information.

Sincerely,

Eugene Dacus, **Acting** Director
Office of Congressional Affairs

Enclosure:
Federal Register notice

cc: Senator **David Vitter**

Comment [SGB2]: Revise all the letters to reflect the 114th Congress.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-14-0100: Final Rule: Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Transportation Requirements (RIN 3150-AI11)

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below XX Attached XX None _____

I approve publication in the *Federal Register* of the final rule (Enclosure 1 to SECY-14-0100), subject to the edits attached. I further certify that this final rule, if adopted, will not have a significant impact on a substantial number of small entities. Consistent with agency practice, relevant guidance documents should be updated and available for release concurrent with publication of the revised final rule or, failing that, as soon as possible thereafter.


SIGNATURE

2/11/15
DATE

Entered in "STARS" Yes  No _____

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-AI11

[NRC-2008-0198]

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is amending its regulations for the packaging and transportation of radioactive material. These amendments make conforming changes to the NRC's regulations based on the 2009 update to the International Atomic Energy Agency's (IAEA) standards for the international transportation of radioactive material and maintain consistency with the DOT's regulations. In addition, these amendments re-establish restrictions on materials that qualify for the fissile material exemption, clarify requirements, update administrative procedures, and make editorial changes.

doing so would require significant changes to the NRC rule, and it would need to be re-published for further comment. The NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT, rather than further delay finalizing this rulemaking.

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.

Fissile Material Exemption

The NRC is re-establishing restrictions on material which that will qualify for the 10 CFR 71.15 fissile material exemption. In 10 CFR 71.15 ("Exemption from classification as fissile material"), the exemption in paragraph (d) is being revised. The 10 CFR 71.15 exemptions were formerly set forth in 10 CFR 71.53. In 1997, the NRC issued an emergency final rule (62 FR 5907; February 10, 1997) that revised the 10 CFR 71.53 regulations on fissile material exemptions and general license provisions that apply to fissile material.

Agreement States. Agreement States will need to update their regulations, as appropriate, at which time those licensees in Agreement States will need to meet the revised Agreement State regulations.

C. What Changes are Being Made to Increase the Compatibility with the IAEA's Regulations, TS-R-1, and the Consistency with the DOT's Regulations?

The NRC is revising its regulations in 10 CFR part 71 to be more consistent or compatible with the international transportation regulations. These changes also improve or maintain consistency between 10 CFR part 71 and the DOT's regulations to maintain a consistent framework for the transportation and packaging of radioactive material. To accomplish these goals, the NRC is revising 10 CFR part 71 as follows:

1. 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.
2. The NRC is adopting the scoping statement paragraph 107(f) of TS-R-1, 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 change, a definition of "contamination" corresponding to the definition in TS-R-1 is added to § 71.4.
3. The following definitions in 10 CFR 71.4 ("Definitions") 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." When the NRC last revised subsection (1)(i) of the definition for LSA material, the NRC added the modifier "not," which resulted in this component of the NRC definition being inconsistent with the DOT and IAEA definitions. The NRC is correcting this so that LSA material includes material intended to be processed for its

10. Footnote a to Table A-1 is revised to include the list of parent radionuclides whose A_1 and A_2 values include contributions from daughter radionuclides with half-lives of less than 10 days. These additions conform to footnote a to Table 2, "Basic Radionuclide Values," in TS-R-1

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 but do not appear within Table A-1.

11. Footnote c to Table A-1 is moved to the A_1 values and revised to clarify that only the activity for iridium-192 (Ir-192) in special form may 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, the activity limit in Table A-2 for exempt consignment for tellurium-121m (Te-121m) is revised to be consistent with the new IAEA value in TS-R-1.

13. The list of parent radionuclides and their progeny included in secular equilibrium in footnote b to Table A-2 is revised to be consistent with the list accompanying Table 2 in TS-R-1.

14. The descriptive language in Table A-3, "General Values for A_1 and A_2 ," of appendix A under the heading "Contents" is revised to be consistent with the IAEA descriptions in Table 3, "Basic Radionuclide Values for Unknown Radionuclides or Mixtures," in TS-R-1(2009 edition). "Only alpha emitting nuclides are known to be present" is replaced with "Alpha emitting nuclides, but no neutron emitters, are known to be present." "No relevant data are available" is replaced with "Neutron emitting nuclides are known to be present or no relevant data are available." Additionally, footnote a is added to the new language "Alpha emitting nuclides, but no neutron emitters, are known to be present" stipulating that if beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 terabecquerel (TBq) (2.7 Ci) should be used.

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

The NRC is revising its 10 CFR 71.14(a)(1) exemption for natural materials and ores containing naturally occurring radionuclides to reflect changes in the scope of TS-R-1.

The TS-R-1 includes statements that describe its activities included within the scope of this IAEA regulation. It also 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 materials are natural materials and ores containing naturally occurring radionuclides. These natural materials and ores are not intended to be processed for their radionuclides and are classified as non-TS-R-1 materials, provided that the activity concentration for the material does not exceed 10 times the activity concentration for exempt material specified in Table A-2 of Appendix A.

The NRC previously established its 10 CFR 71.14(a)(1) exemption from the requirements of 10 CFR part 71 for licensees who ship or carry that exempts licensees from the requirements of 10 CFR part 71 for certain natural materials and ores designated as. This 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. The exemption allows the transport of certain qualifying natural material or ore that qualifies for the exemption without the material being regulated as a hazardous material during transportation. However, all applicable NRC regulations in other 10 CFR parts continue to apply to these natural materials and ores. The current exemption in § 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 updating this exemption to include the shipment of natural materials and ores containing naturally occurring radionuclides that have been processed, which will retain consistency with the DOT's regulations and harmonize the NRC's regulations with the current TS-R-1. This exemption

continues 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 of Appendix A.

The NRC is also revising the definition of LSA-I material in 10 CFR 71.4 (i.e., material intended to be processed for its radionuclides) so that it applies to uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides 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, will now apply to LSA-I material.

With the revision of the definition of LSA-I material, uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for these radionuclides may be able to qualify for the low-level material exemption in § 71.14(b)(3), provided that the other restrictions are satisfied. The restrictions include: 1) the package contains only LSA-I or Surface Contaminated Object (SCO)-I material or 2) ~~that~~ the LSA or SCO material has an external radiation dose rate of less than 10 millisieverts per hour (mSv/h) (1 rem per hour (rem/h)) at a distance of 3 meters from the unshielded material. Section 71.14 provides an exemption from the requirements of 10 CFR part 71, with the exception of §§ 71.5 and 71.88. Section 71.5 references the DOT's regulations in 49 CFR parts 107, 171 through 180, and 390 through 397. If the DOT's regulations are not applicable to a shipment of licensed material, then § 71.5 requires licensees to conform to the referenced DOT standards and regulations to the same extent as if the shipment were subject to the DOT's regulations. Section 71.88 will continue to apply to the material because its applicability is not limited by any of the exemptions in 10 CFR part 71.

K. How do the Requirements in Subpart H, “Quality Assurance,” Change with the Removal of Footnote 2 in 10 CFR 71.103?

The NRC is removing footnote 2 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 apply to whatever design, fabrication, assembly, and testing of a package is accomplished before a package approval is issued. The terms “certificate holder” and “applicant for a CoC” were added to the requirements in subpart H in a previous rulemaking to make explicit the application of those quality assurance requirements to certificate holders and applicants for a CoC. Although removing the footnote will not change the quality assurance requirements, other changes to subpart H in this rulemaking clarify which requirements apply to users of NRC certified packaging and which apply to applicants for, or holders of CoCs, which are the entities that are performing design, fabrication, assembly, and testing of the package before a package approval is issued.

L. What Changes are Being Made to General Licenses?

The NRC is changing the requirements for general licenses on the use of an NRC-approved package (§ 71.17) and use of a foreign-approved package (§ 71.21). In § 71.17, the NRC is revising the general license requirements to clarify the conditions for obtaining a general license and the responsibilities of the general licensee. A quality assurance program approved by the NRC ~~which~~that satisfies the provisions of subpart H of 10 CFR part 71 is required in order to be granted the general license. The changes clarify that the licensee is responsible for maintaining copies of the appropriate documents, such as the CoC, or other approval of the package, the documents associated with the use and maintenance of the

In order to ensure criticality safety, the exemptions were evaluated using assumptions that, as part of the criticality safety assessment for package designs approved to transport fissile material, the fissile material can be released from the packaging during transport, may

reconfigure into a worst-case geometric arrangement, may combine with material from other transport vehicles, and may be subject to the fire and water immersion.

The reactivity of uranium enriched in U-235 depends on the level of enrichment, the presence of moderators, and heterogeneity effects. Hydrogen is the most efficient moderator and water is the most common material containing large quantities of hydrogen; therefore, water is the typical moderating material of interest in criticality safety. The maximum enrichment in U-235 allowed to qualify for the fissile material exemption in § 71.15(d) is 1 percent by weight, which is slightly less than the minimum critical enrichment for an infinite, homogeneous mixture of enriched uranium and water.⁴ The minimum critical enrichment is the enrichment necessary for a system to have a neutron multiplication factor of one. Systems containing homogeneous mixtures of uranium enriched to less than the minimum critical enrichment (e.g., a homogenous mixture of uranium enriched to a maximum of 1 percent) are not capable of obtaining criticality, irrespective of the mass or size of the system. The fissile material exemption in § 71.15(d) also limits the quantity of some less common moderating materials (beryllium, graphite, and hydrogenous material enriched in deuterium), because the presence of these materials has the potential to reduce the minimum critical enrichment, thereby increasing the potential for criticality with uranium of lower enrichment. Therefore, homogeneous materials containing uranium enriched to no more than 1 percent by weight and subject to the noted restrictions on moderators are inherently safe from a potential criticality and do not need to be limited by mass

⁴ H.C. Paxton and N. L. Pruvost, Critical Dimensions of Systems Containing U-235, Pu-239, and U-233, LA-10860-MS, Los Alamos National Laboratory, (1987).

need not be licensed under this chapter.”

Response: The NRC finds that the wording of the new exemption provision in 10 CFR 71.14(a)(3), as proposed, is sufficiently clear, and thus is not accepting the proposed modification. The scope of this new exemption is limited to the NRC’s part 71 transportation regulations. The NRC licensees are not being exempted from meeting the requirements stated in other applicable 10 CFR parts, (also see response to Comment A.1 and Comment D.4.).

A.2 Special Form Radioactive Material

Comment: Although one commenter voiced general support for the revised definition of *special form radioactive material* in § 71.4, another commenter was concerned that the new language being added to ~~its~~ revised paragraph (3) of the definition, “... and special form material that was successfully tested before [INSERT EFFECTIVE DATE OF FINAL RULE]...,” is unclear. The commenter noted that the existing language contained within paragraph (3) uses the term “special form encapsulation” and that this term was consistent with the commenter’s understanding of the intent of these changes as discussed in the *Federal Register* notice. However, the commenter stated that using the term special form “material,” rather than “encapsulation” is ambiguous as to whether the revised language is meant to apply to a special form that is a single solid piece of material only, or whether the rule aims to grandfather special form designs including encapsulations that were designed and constructed after the earlier dates cited in the paragraph. For clarity and consistency, the commenter recommended replacing the proposed “special form material” term with the term “special form encapsulation” in paragraph (3) of the revised definition.

Response: Special form radioactive material may be either encapsulated or a single solid piece; using the term “special form encapsulation” would not refer to a single solid

piece. The NRC is choosing to use the broader “special form material” term so that the revised definition will—1) permit the continued use of encapsulations authorized under the existing definition, and 2) cover special form materials as authorized in the DOT’s regulation (see 49 CFR 173.469(e)).

A.3 Other

Comment: One commenter recommended adding a new definition to 10 CFR 71.4 to define “radiation level” as: “the radiation dose-equivalent rate expressed in millisieverts per hour or mSv/h (millirem per hour or mrem/h). It consists of the sum of the dose equivalent rates from all types of ionizing radiation present including alpha, beta, gamma, and neutron radiation. Neutron flux densities may be used to determine neutron radiation levels according to Table 1.”

Response: The NRC declines to add the requested definition of “radiation level” to 10 CFR 71.4 for the following reasons. “Radiation” is already defined in 10 CFR part 20 (“Standards for Protection Against Radiation”), and this term includes all the types of ionizing radiation that are referenced in the comment. Additionally, the term “radiation” applies to all types of NRC licensees, in accordance with the 10 CFR 20.1002 scoping provisions.

B. Exemptions for Low-level Materials

Comment: One commenter stated that the discussion contained within the *Federal Register* notice appears to indicate that natural material that has been processed could qualify for the exemption if it is not included in a manufactured product, such as an article, instrument, component of a manufactured article or instrument, or consumer item. The commenter was concerned that there appears to be a discrepancy between this statement and the language in the proposed rule regarding intent to be processed for the use of

Comment: One commenter noted that the IAEA's 2012 edition of SSR-6 did not include the phrase "or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides." The commenter was concerned that given the length of time it can take to promulgate a rulemaking, the NRC should consider revising its proposed 10 CFR 71.14(a)(1) text to be consistent with the current SSR-6. Specifically, Section 107 of SSR-6 states that regulations do not apply to any of the following:

"(f) Natural material and ores containing naturally occurring radionuclides, which may have been processed, provided the activity concentration of the material does not exceed 10 times the values specified in Table 2, or calculated in accordance with paras 403(a) and 404–407. For natural materials and ores containing naturally occurring radionuclides that are not in secular equilibrium the calculation of the activity concentration shall be performed in accordance with para. 405.⁴"

The commenter thus recommended revising the proposed 10 CFR 71.14(a)(1) provisions to exempt "Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have been processed, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Appendix A, Table A-2, or Table A-3, of this part."

Response: The NRC is choosing not to make the commenter's recommended revisions. The DOT/NRC MOU recognizes the DOT as the federal agency responsible for the definition of radioactive material in transit. After careful consideration, the DOT chose not to remove the intended use-clause in its current proposed rule, in part because the rule is intended to achieve compatibility with the 2009 Edition of the IAEA regulations, not the 2012 Edition. Publication of the 2012 Edition in October 2012, did not allow adequate time for the NRC and DOT to effectively evaluate the changes as part of this rulemaking effort. There are many other changes in the 2012 Edition that also are not reflected in either the proposed DOT or NRC rulemakings. Rather than further delay finalizing this rulemaking, Gcchanges in

the DOT and NRC regulations to reflect the IAEA's 2012 edition of SSR-6 will be addressed considered in subsequent rulemakings. The NRC is choosing not to make such changes unilaterally, since doing so would create a conflict between DOT and NRC regulatory requirements. Not only would conflicting requirements and definitions contradict long-standing policy to establish a uniform, national hazardous material transportation safety system, such conflicts could likely create uncertainty within the regulated community and prove to be unenforceable.

C. Quality Assurance Program

Comment: Three commenters voiced support of proposed changes to 10 CFR part 71 relating to the quality assurance program approvals. One of these commenters stated that the proposed changes would 1) streamline the process of maintaining an approved program, 2) contribute to implementation of continued improvement efforts by the approval holders, and 3) ensure the level of safety afforded shipments will not be diminished. Another of these commenters believed that the proposal would better risk inform U.S. regulations and harmonize the U.S. regulations with international rules. A different commenter disagreed with the proposed approach and recommended that 10 CFR 71.38(c) only extend the expiration dates to 10 years. The proposed rule would have removed the quality assurance expiration provision in order to minimize the impact on the applicants while still requiring a licensee to submit all documentation, including the quality assurance program, for review when renewing their license.

Response: The NRC expects that parties who already have an approved QA program will receive an updated completed approval form identifying the removal of the expiration. Essentially, this is no different than what has been expected of the receipt of the previous QA

program approval, except that this will be the last and only receipt if no changes affecting QA commitments occur. For future applicants, the original QA program approval will be issued with no expiration date. But any changes affecting QA commitments must still be submitted to the NRC for approval, including any such changes that are part of a license renewal request. The

NRC thus finds that there is no need to adopt the commenter's recommended 10-year expiration provision.

Comment: One commenter stated that while it agreed with the philosophy of the proposed 10 CFR 71.106, which will allow a licensee to make changes to the quality assurance program, it recommended mirroring 10 CFR 35.26 by adding the following rule language:

- 1) The revision has been reviewed and approved by management.
- 2) Affected individuals are instructed on the revised program before the changes are implemented.
- 3) A record of this instruction be created and maintained."

Response: The NRC agrees with the commenter that management review and approval, appropriate instruction or training prior to implementation, and record keeping, are key attributes of effectively managing changes. The specific language referenced from 10 CFR 35.26 has not been added because these requirements are already embedded in the existing regulations.

The NRC finds that the first two recommended additions to proposed 10 CFR 71.106 are not necessary, because they are adequately addressed by the existing general provisions of 10 CFR 71.105 ("Quality assurance program"). Regarding management review and approval of non-substantive revisions to a quality assurance program, existing § 71.105(d) states in relevant part that management of organizations involved in a licensee's or CoC holder's quality

independent inspectors prior to shipment in a licensed package.” Because this comment raises issues that are outside the scope of this rulemaking, it will not be further addressed here.

Comment: A commenter stated that containers of activated metal loaded underwater cannot be sealed because the water must be allowed to drain from the containers prior to shipment. Since activated metal is not dispersible, sealing of the waste container should not be required.

Response: The NRC’s proposed rule did not include such a requirement. Because this comment raises issues that are outside the scope of this rulemaking, it will not be further addressed here.

D.3 Activity Limit for Type B Packages

Comment: One commenter stated concerns that the new calculations to limit the activity that a licensed Type B package may contain are not risk informed for LSA group II low-level waste that commercial power plants routinely ship. The commenter believes that these new calculations were imposed because of an incident with an iridium source, and therefore, such calculation requirements should be limited to the shipment of concentrated radioactive sources similar to the one involved in the event.

Response: The commenter misconstrues the proposed change in the calculations regarding iridium. The NRC is not proposing any changes regarding when Type B packages are required for LSA shipments. Under existing regulations, Type B packaging is essentially required for LSA when the material has an external radiation dose greater than 10 mSv/h (1 rem/h), at a distance of 3 meters from the unshielded material. Therefore, the need for Type B packaging for LSA material is directly based on the dose rate from, not the activity of, the material. Further, iridium sources do not meet the existing 10 CFR Part 71.4 definition of

definition of contamination in the DOT's regulations in 49 CFR 173 and TS-R-1.

The definition of "Criticality Safety Index (CSI)" has been revised to be more consistent with the definition in the DOT's regulations in 49 CFR 173 and TS-R-1 by addressing overpacks and freight containers in the definition.

The definition of "Low Specific Activity (LSA) material" has been revised so that it is more consistent with the definition in the DOT's regulations in 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 that is intended to be processed for the use of the uranium, thorium, and other naturally occurring radionuclides. In paragraph (1)(ii), the definition is changed to clarify consideration of compounds or mixtures regardless of the form (i.e., solid or liquid).

The definition of "Special form radioactive material" has been 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 **[INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. The reference to the version of 10 CFR part 71 in effect on March 31, 1996, is corrected by changing 1983 to 1996.

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

Section 71.6 Information collection requirements: OMB approval.

Paragraph (b) is revised to add § 71.106 to the list of sections with information collections.

licensees to comply “with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H” of 10 CFR part 71. Because the quality

assurance provisions in subpart H for design, construction, and fabrication activities are not applicable to a general licensee, the exemption was ~~superfluous~~not needed.

Section 71.31 Contents of application.

In paragraph (b), the reference to § 71.13 is changed to § 71.19. This change was inadvertently omitted during a previous rulemaking, when certain sections were renumbered.

Section 71.38 Renewal of a certificate of compliance.

The title of this section is revised to remove the reference to the renewal of quality assurance program approvals. The section is revised to be limited to the renewal of CoCs by removing all references to quality assurance program approvals. The NRC is changing its practice regarding the duration of quality assurance program approvals. Quality assurance program approvals will not have an expiration date and the NRC will revise the current quality assurance program approvals so that they will not have an expiration date. The renewal of a quality assurance program approval is unnecessary. Paragraphs (a), (b) and (c) have also been revised for clarity.

Section 71.70 Incorporations by reference.

This section is added to incorporate by reference the consensus standards referenced in § 71.75: ISO 9978:1992(E), “Radiation protection—Sealed radioactive sources—Leakage test methods”; and ISO 2919:1999(E), “Radiation protection—Sealed radioactive sources—General

that the revised program incorporating the change will continue to satisfy the requirements of subpart H of 10 CFR 71 that apply.

Paragraph (a)(2) will require that each holder of a quality assurance program approval maintain quality assurance program changes as records. These records will need to be maintained as required in § 71.135.

Paragraph (b) will allow the holder of a quality assurance program approval to make changes to its quality assurance program that will not reduce its commitments to the NRC and identify the changes that will not be considered as reducing its commitments to the NRC.

Paragraph (c) will require that records be maintained documenting any changes to the quality assurance program.

Section 71.135 Quality assurance records.

This section is revised to include those quality assurance records that apply to changes that are made to previously approved quality assurance programs. The second sentence is revised to include in the list of the types of records to be maintained the changes to the quality assurance program as required by new § 71.106.

Appendix A Determination of A_1 and A_2 .

In paragraphs IV.a. through IV.f., the equations and accompanying text are revised to make minor corrections. In paragraphs IV.a. and IV.b., the description of the equations will 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.

Current paragraphs IV.c. through IV.f. are redesignated as paragraphs IV.d. through IV.g. New paragraph IV.c. is added and provides an equation to be used for determining the

references the quality assurance programs for industrial radiographers is updated by changing § 71.12(b) to § 71.17(b).

XV. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC uses the consensus standards identified as follows and will incorporate them by reference. The NRC is adopting ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), for the Class 4 and Class 5 impact tests and the Class 6 temperature test; and ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), for the leaktightness tests.

In other portions of this final rule, the NRC is revising requirements that do not constitute the establishment of a standard that establishes generally applicable requirements. These revisions to the NRC's requirements include changes to: 1) the scope of material falling under an existing exemption for natural materials and ores containing naturally occurring radionuclides at an activity concentration below a specified value, 2) conditions on general licenses, 3) the oversight of quality assurance programs, and 4) the removal of transitional arrangements for previously approved packages.

XVI. Availability of Guidance.

In the Rules and Regulations section of this issue of the *Federal Register*, the NRC is issuing revised implementation guidance for this rule, RG 7.10, Revision 3, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material" (Docket ID NRC-2013-0082). The guidance is also available in ADAMS under Accession No. ML14064A505. Revised RG 7.10 is intended to describe a proposed method that the NRC staff considers acceptable for use in complying with the NRC's proposed amendments to its regulations on quality assurance programs related to transport of radioactive materials. Because the regulatory analysis for the final rule provides sufficient explanation for the rule and its implementing guidance, a separate regulatory analysis was not prepared for RG 7.10.

List of Subjects In 10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Nuclear materials, Packaging and containers, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 71.

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

(iii) Radioactive material other than fissile material, for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with appendix A.

(2) LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

(3) LSA-III. Non-powder Solids (e.g., consolidated wastes, activated materials),
~~excluding powders~~, that satisfy the requirements of § 71.77, in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for 7 days will not exceed $0.1 A_2$; and

(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed $2 \times 10^{-3} A_2/g$.

* * * *

Special form radioactive material means radioactive material that satisfies the following conditions:

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Ostendorff

SUBJECT: **SECY-14-0100: Final 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 X None _____

I approve, subject to the attached edits publishing the Final Rule: 10 CFR Part 71 in the Federal Register, to harmonize our transportation regulations with the current DOT regulations, with the 2009 IAEA requirements, and to make additional safety and administrative changes. Additionally, I certify that this rule will not have significant impact on a substantial number of small entities.

There were only a few commenters, and the staff addressed all of the comments. However, there were some comments that the staff should have addressed differently. Specifically, for the staff to be clear that the NRC is harmonizing with the 2009 IAEA requirements not the current IAEA requirements, staff should change the title as indicated in the attached edits.



SIGNATURE

10/30/14

DATE

Entered on "STARS" Yes X No _____

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-AI11

[NRC-2008-0198]

Revisions to Transportation Safety Requirements and Harmonization with the 2009

International Atomic Energy Agency Transportation Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is amending its regulations for the packaging and transportation of radioactive material. These amendments make conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) 2009 standards for the international transportation of radioactive material and maintain consistency with the DOT's regulations. In addition, these amendments re-establish restrictions on material that qualifies for the fissile material exemption, clarify requirements, update administrative procedures, and make editorial changes.

doing so would require significant changes to the NRC rule, and it would need to be re-published for further comment. The NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT, rather than further delay finalizing this rulemaking.

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

Fissile Material Exemption

The NRC is re-establishing restrictions on material which material that will qualify for the 10 CFR 71.15 fissile material exemption. In 10 CFR 71.15 ("Exemption from classification as fissile material"), the exemption in paragraph (d) is being revised. The 10 CFR 71.15 exemptions were formerly set forth in 10 CFR 71.53. In 1997, the NRC issued an emergency final rule (62 FR 5907; February 10, 1997) that revised the 10 CFR 71.53 regulations on fissile material exemptions and general license provisions that apply to fissile material.

programs." This action also changes requirements that are matters of compatibility with Agreement States. Agreement States will need to update their regulations, as appropriate, at which time those licensees in Agreement States will need to meet the revised Agreement State regulations.

C. What Changes are Being Made to Increase the Compatibility with the IAEA's Regulations, TS-R-1, and the Consistency with the DOT's Regulations?

The NRC is revising its regulations in 10 CFR part 71 to be more consistent or compatible with the international transportation regulations. These changes also improve or maintain consistency between 10 CFR part 71 and the DOT's regulations to maintain a consistent framework for the transportation and packaging of radioactive material. To accomplish these goals, the NRC is revising 10 CFR part 71 as follows:

1. 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.
2. The NRC is adopting the scoping statement paragraph 107(f) of TS-R-1, 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 change, a definition of "contamination" corresponding to the definition in TS-R-1 is added to § 71.4.
3. The following definitions in 10 CFR 71.4 ("Definitions") 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." When the NRC last revised subsection (1)(i) of the definition for LSA material, the NRC added the modifier "not," which resulted in this component of the NRC definition being inconsistent with the DOT and IAEA definitions. The

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

The NRC is revising its 10 CFR 71.14(a)(1) exemption for natural materials and ores containing naturally occurring radionuclides to reflect changes in the scope of TS-R-1.

The TS-R-1 includes statements that describe its activities included within the scope of this IAEA regulation. It also 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 materials are natural materials and ores containing naturally occurring radionuclides. These natural materials and ores are not intended to be processed for their radionuclides and are classified as non-TS-R-1 materials, provided that the activity concentration for the material does not exceed 10 times the activity concentration for exempt material specified in Table A-2 of Appendix A.

The NRC previously established its 10 CFR 71.14(a)(1) exemption from the requirements of 10 CFR part 71 for licensees who ship or carry that exempts licensees from the requirements of 10 CFR part 71 for certain natural materials and ores—designated as This 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, The exemption and allows the transport of natural material or ore that qualifies for the exemption without the material's being regulated as a hazardous material during transportation. However, all applicable NRC regulations in other 10 CFR parts continue to apply to these natural materials and ores. The current exemption in § 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 updating this exemption to include the shipment of natural materials and ores containing naturally occurring radionuclides that have been processed, which will retain consistency with the DOT's regulations and harmonize the NRC's regulations with the current TS-R-1. This exemption continues to be

radionuclides whose activity concentrations may be up to 10 times the activity concentration specified in Table A-2 of Appendix A.

The NRC is also revising the definition of LSA-I material in 10 CFR 71.4 (i.e., material intended to be processed for its radionuclides) so that it applies to uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides 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, will now apply to LSA-I material.

With the revision of the definition of LSA-I material, uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for these radionuclides may be able to qualify for the low-level material exemption in § 71.14(b)(3), provided that the other restrictions are satisfied. The restrictions include: 1) the package contains only LSA-I or Surface Contaminated Object (SCO)-I material or 2) ~~that~~ the LSA or SCO material has an external radiation dose rate of less than 10 millisieverts per hour (mSv/h) (1 rem per hour (rem/h)) at a distance of 3 meters from the unshielded material. Section 71.14 provides an exemption from the requirements of 10 CFR part 71, with the exception of §§ 71.5 and 71.88. Section 71.5 references the DOT's regulations in 49 CFR parts 107, 171 through 180, and 390 through 397. If the DOT's regulations are not applicable to a shipment of licensed material, then § 71.5 requires licensees to conform to the referenced DOT standards and regulations to the same extent as if the shipment were subject to the DOT's regulations. Section 71.88 will continue to apply to the material because its applicability is not limited by any of the exemptions in 10 CFR part 71.

Natural material or ore that has been incorporated into a manufactured product, such as an article, instrument, component of a manufactured article or instrument, or consumer item, will

material, the fissile material can be released from the packaging during transport, may

Comment [TEB8]: spacing

reconfigure into a worst-case geometric arrangement, may combine with material from other transport vehicles, and may be subject to the fire and water immersion.

The reactivity of uranium enriched in U-235 depends on the level of enrichment, the presence of moderators, and heterogeneity effects. Hydrogen is the most efficient moderator and water is the most common material containing large quantities of hydrogen; therefore, water is the typical moderating material of interest in criticality safety. The maximum enrichment in U-235 allowed to qualify for the fissile material exemption in § 71.15(d) is 1 percent by weight, which is slightly less than the minimum critical enrichment for an infinite, homogeneous mixture of enriched uranium and water.⁴ The minimum critical enrichment is the enrichment necessary for a system to have a neutron multiplication factor of one. Systems containing homogeneous mixtures of uranium enriched to less than the minimum critical enrichment (e.g., a homogenous mixture of uranium enriched to a maximum of 1 percent) are not capable of obtaining criticality, irrespective of the mass or size of the system. The fissile material exemption in § 71.15(d) also limits the quantity of some less common moderating materials (beryllium, graphite, and hydrogenous material enriched in deuterium), because the presence of these materials has the potential to reduce the minimum critical enrichment, thereby increasing the potential for criticality with uranium of lower enrichment. Therefore, homogeneous materials containing uranium enriched to no more than 1 percent by weight and subject to the noted restrictions on moderators are inherently safe from a potential criticality and do not need to be limited by mass or size to be subcritical during transport. However, uranium enriched to less than 5 percent by weight is most reactive when it is in a heterogeneous configuration; therefore, the minimum

⁴ H.C. Paxton and N. L. Pruvost, Critical Dimensions of Systems Containing U-235, Pu-239, and U-233, LA-10860-MS, Los Alamos National Laboratory, (1987).

(see 49 CFR 173.469(e)).

A.3 Other

Comment: One commenter recommended adding a new definition to 10 CFR 71.4 to define "radiation level" as: "the radiation dose-equivalent rate expressed in millisieverts per hour or mSv/h (millirem per hour or mrem/h). It consists of the sum of the dose equivalent rates from all types of ionizing radiation present including alpha, beta, gamma, and neutron radiation. Neutron flux densities may be used to determine neutron radiation levels according to Table 1."

Response: The NRC declines to add the requested definition of "radiation level" to 10 CFR 71.4 for the following reasons. "Radiation" is already defined in 10 CFR part 20

~~(“Standards for Protection Against Radiation”)~~, and this term includes all the types of ionizing radiation that are referenced in the comment. Additionally, the term "radiation" applies to all types of NRC licensees, in accordance with the 10 CFR 20.1002 scoping provisions.

Comment [TEB9]: spacing

B. Exemptions for Low-level Materials

Comment: One commenter stated that the discussion contained within the *Federal Register* notice appears to indicate that natural material that has been processed could qualify for the exemption if it is not included in a manufactured product, such as an article, instrument, component of a manufactured article or instrument, or consumer item. The commenter was concerned that there appears to be a discrepancy between this statement and the language in the proposed rule regarding intent to be processed for the use of radionuclides.

Response: The comment does not specify the exemption provisions that are of

therefore, it is clear to the user when the exemption provisions in 71.14(b)(3)(ii) would apply.

Comment: One commenter noted that the IAEA's 2012 edition of SSR-6 did not include the phrase "or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides." The commenter was concerned that given the length of time it can take to promulgate a rulemaking, the NRC should consider revising its proposed 10 CFR 71.14(a)(1) text to be consistent with the current SSR-6. Specifically, Section 107 of SSR-6 states that regulations do not apply to any of the following:

"(f) Natural material and ores containing naturally occurring radionuclides, which may have been processed; provided the activity concentration of the material does not exceed 10 times the values specified in Table 2, or calculated in accordance with paras 403(a) and 404–407. For natural materials and ores containing naturally occurring radionuclides that are not in secular equilibrium the calculation of the activity concentration shall be performed in accordance with para. 405."

The commenter thus recommended revising the proposed 10 CFR 71.14(a)(1) provisions to exempt "Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have been processed, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Appendix A, Table A-2, or Table A-3, of this part."

Response: The NRC is choosing not to make the commenter's recommended revisions. The DOT/NRC MOU recognizes the DOT as the federal agency responsible for the definition of radioactive material in transit. After careful consideration, the DOT chose not to remove the intended use-clause in its current proposed rule, in part because the rule is intended to achieve compatibility with the 2009 Edition of the IAEA regulations, not the 2012 Edition. Publication of the 2012 Edition in October 2012, did not allow adequate time for the NRC and DOT to effectively evaluate the changes as part of this rulemaking effort. There are many other changes in the 2012 Edition that also are not reflected in either the proposed

DOT or NRC rulemakings. Changes in the DOT and NRC regulations to reflect the IAEA's 2012 edition of SSR-6 The NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT, rather than further delay finalizing this rulemaking will be addressed in subsequent rulemakings. The NRC is choosing not to make such changes unilaterally, since doing so would create a conflict between DOT and NRC regulatory requirements. Not only would conflicting requirements and definitions contradict long-standing policy to establish a uniform, national hazardous material transportation safety system, such conflicts could likely create uncertainty within the regulated community and prove to be unenforceable.

C. Quality Assurance Program

Comment: Three commenters voiced support of proposed changes to 10 CFR part 71 relating to the quality assurance program approvals. One of these commenters stated that the proposed changes would 1) streamline the process of maintaining an approved program, 2) contribute to implementation of continued improvement efforts by the approval holders, and 3) ensure the level of safety afforded shipments will not be diminished. Another of these commenters believed that the proposal would better risk inform U.S. regulations and harmonize the U.S. regulations with international rules. A different commenter disagreed with the proposed approach and recommended that 10 CFR 71.38(c) only extend the expiration dates to 10 years. The proposed rule would have removed the quality assurance expiration provision in order to minimize the impact on the applicants while still requiring a licensee to submit all documentation, including the quality assurance program, for review when renewing their license.

Response: The NRC expects that parties who already have an approved QA program

NRC for approval, including any such changes that are part of a license renewal request. The

NRC thus finds that there is no need to adopt the commenter's recommended 10-year expiration provision.

Comment [TEB10]: spacing

Comment: One commenter stated that while it agreed with the philosophy of the proposed 10 CFR 71.106, which will allow a licensee to make changes to the quality assurance program, it recommended mirroring 10 CFR 35.26 by adding the following rule language:

- 1) The revision has been reviewed and approved by management.
- 2) Affected individuals are instructed on the revised program before the changes are implemented.

3) A record of this instruction be created and maintained."

Response: The NRC agrees with the commenter that management review and approval, appropriate instruction or training prior to implementation, and record keeping, are key attributes of effectively managing changes. The specific language referenced from 10 CFR 35.26 has not been added because these requirements are already embedded in the existing regulations.

The NRC finds that the first two recommended additions to proposed 10 CFR 71.106 are not necessary, because they are adequately addressed by the existing general provisions of 10 CFR 71.105 ("Quality assurance program"). Regarding management review and approval of non-substantive revisions to a quality assurance program, existing § 71.105(d) states in relevant part that management of organizations involved in a licensee's or CoC holder's quality assurance program "shall review regularly the status and adequacy of that part of the quality assurance program they are executing." The NRC finds that this existing requirement adequately ensures management oversight of quality assurance programs. Regarding the

Section 71.4 Definitions.

The definition of "contamination" has been added and is now consistent with the definition of contamination in the DOT's regulations in 49 CFR 173 and TS-R-1.

The definition of "Criticality Safety Index (CSI)" has been revised to be more consistent with the definition in the DOT's regulations in 49 CFR 173 and TS-R-1 by addressing overpacks and freight containers in the definition.

The definition of "Low Specific Activity (LSA) material" has been revised so that it is more consistent with the definition in the DOT's regulations in 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 that is intended to be processed for the use of the uranium, thorium, and other naturally occurring radionuclides. In paragraph (1)(ii), the definition is changed to clarify consideration of compounds or mixtures regardless of the form (solid or liquid).

The definition of "Special form radioactive material" has been 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 [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The reference to the version of 10 CFR part 71 in effect on March 31, 1996, is corrected by changing 1983 to 1996.

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

Section 71.6 Information collection requirements: OMB approval.

Paragraph (b) is revised to add § 71.106 to the list of sections with information

Section 71.14 Exemption for low-level materials.

Paragraph (a)(1) has been 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 are considered to be 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 cannot exceed 10 times the activity concentration values, and the material cannot be intended to be processed for the use of the radionuclides. A reference to Table A-3 in appendix A is added as a source of activity concentration values that may be used to determine whether natural material or ore will qualify for the exemption. Table A-3 provides activity concentration values for exempt material that are used for individual radionuclides whose identities are known but which are not listed in Table A-2.

Paragraph (a)(2) has been revised to add a reference to Table A-3 in appendix A. Table A-3 provides activity concentration values for exempt material that are used for individual radionuclides whose identities are known but which are not listed in Table A-2.

Paragraph (a)(3) has been 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" has been added to § 71.4.

sentence, which provided an exemption from quality assurance provisions in subpart H for design, construction, and fabrication activities. As revised, § 71.21(d)(2) will require general licensees to comply "with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H" of 10 CFR part 71. Because the quality

Comment [TEB8]: spacing

assurance provisions in subpart H for design, construction, and fabrication activities are not applicable to a general licensee, the exemption was ~~superfluousnot needed~~.

Section 71.31 Contents of application.

In paragraph (b), the reference to § 71.13 is changed to § 71.19. This change was inadvertently omitted during a previous rulemaking, when certain sections were renumbered.

Section 71.38 Renewal of a certificate of compliance.

The title of this section is revised to remove the reference to the renewal of quality assurance program approvals. The section is revised to be limited to the renewal of CoCs by removing all references to quality assurance program approvals. The NRC is changing its practice regarding the duration of quality assurance program approvals. Quality assurance program approvals will not have an expiration date and the NRC will revise the current quality assurance program approvals so that they will not have an expiration date. The renewal of a quality assurance program approval is unnecessary. Paragraphs (a), (b) and (c) have also been revised for clarity.

Section 71.70 Incorporations by reference.

This section is added to incorporate by reference the consensus standards referenced in

Section 71.85 Preliminary determinations.

In paragraphs (a), (b), and (c), "licensee" is replaced by "certificate holder." The NRC experience is that these determinations are performed by the certificate holders who manufacture the package. This change will make the requirements consistent with current practice, because 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 address 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 are responsible for ensuring that these determinations have been made before their first use of the packaging.

Section 71.91 Records.

In paragraph(a), the reference to § 71.10 is changed to § 71.14. This reference was not updated when § 71.10 was redesignated as § 71.14.

Section 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 CoC are subject to the quality assurance requirements. Note that consistent with the existing 71.101(c)(1) QA-program-approval requirements, 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(e)(1) QA program-approval requirements that are not being revised.

Paragraph (a) will establish the requirements that will apply when a holder of a quality assurance program approval intends to make a change in its quality assurance program that would reduce its commitments to the NRC. The holder of a quality assurance program approval will be required to identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change will continue to satisfy the requirements of subpart H of 10 CFR 71 that apply.

Paragraph (a)(2) will require that each holder of a quality assurance program approval maintain quality assurance program changes as records. These records will need to be maintained as required in § 71.135.

Paragraph (b) will allow the holder of a quality assurance program approval to make changes to its quality assurance program that will not reduce its commitments to the NRC and identify the changes that will not be considered as reducing its commitments to the NRC.

Paragraph (c) will require that records be maintained documenting any changes to the quality assurance program.

Section 71.135 Quality assurance records.

This section is revised to include those quality assurance records that apply to changes that are made to previously approved quality assurance programs. The second sentence is revised to include in the list of the types of records to be maintained the changes to the quality assurance program as required by new § 71.106.

Appendix A Determination of A₁ and A₂.

In paragraphs IV.a. through IV.f., the equations and accompanying text are revised to make minor corrections. In paragraphs IV.a. and IV.b., the description of the equations will

XVI. Availability of Guidance.

In the Rules and Regulations section of this issue of the *Federal Register*, the NRC is issuing revised implementation guidance for this rule, RG 7.10, Revision 3, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material" (Docket ID NRC-2013-0082). The guidance is also available in ADAMS under Accession No. ML14064A505.

Revised RG 7.10 is intended to describe a proposed method that the NRC staff considers acceptable for use in complying with the NRC's proposed amendments to its regulations on quality assurance programs related to transport of radioactive materials. Because the regulatory analysis for the final rule provides sufficient explanation for the rule and its implementing guidance, a separate regulatory analysis was not prepared ~~for RG for RG~~ 7.10.

Comment [TEB15]: spacing

List of Subjects In 10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Nuclear materials, Packaging and containers, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 71.

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

(iii) Radioactive material other than fissile material, for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with appendix A.

(2) LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

(3) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of § 71.77, in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for 7 days will not exceed $0.1 A_2$; and

(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed $2 \times 10^{-3} A_2/g$.

* * * *

Special form radioactive material means radioactive material that satisfies the following conditions:

- (1) The use of a quality assurance standard approved by the NRC which 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.

Comment [TEB16]: spacing

19. Revise § 71.135 to read as follows:

§ 71.135 Quality assurance records.

The licensee, certificate holder, and applicant for a Certificate of Compliance shall maintain sufficient written records to describe the activities affecting quality. These records

Appendix A to Part 71 – Determination of A_1 and A_2

* * * * *

IV. * * *

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

$$\left| \sum_i \frac{B(i)}{A_1(i)} \leq 1 \right|$$

Comment [TEB17]: fix subscripts in most equations that follow

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:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

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 may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

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 .

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-14-0100: Final 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 X None


SIGNATURE

3/18/15
DATE

Entered on "STARS" Yes ✓ No

Commissioner Baran's Comments on SECY-14-0100: Final Rule: Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements

Subject to the attached edits, I approve the publication in the Federal Register of the final rule that would amend Part 71 of title 10 of the *Code of Federal Regulations*, "Packaging and Transportation of Radioactive Material." I would like to thank the staff for their hard work and diligence in completing this rulemaking effort. Also, I certify that this final rule, if adopted, will not have a significant impact on a substantial number of small entities. Due to the length of time that the rule has been before the Commission, a couple elements of the package need to be updated. In that regard, the staff should update the Congressional letters to reflect the makeup of the current Congress and remove the acting designation from the title of the Director of Congressional Affairs.

Additionally, the Environmental Assessment provided as Enclosure 3 to SECY-14-0100, beginning on page 11, references preliminary results of the International Atomic Energy Agency's coordinated research program on naturally occurring radioactive material. Staff should update this section as indicated in the attached edits to reflect that the final report on this research published in 2013 confirmed the preliminary results.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-AI11

[NRC-2008-0198]

**Revisions to Transportation Safety Requirements and Harmonization with the 2009
International Atomic Energy Agency Transportation Requirements**

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is amending its regulations for the packaging and transportation of radioactive material. These amendments make conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) 2009 standards for the international transportation of radioactive material and maintain consistency with the DOT's regulations. In addition, these amendments re-establish restrictions on material that qualifies for the fissile material exemption, clarify requirements, update administrative procedures, and make editorial changes.

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 of TS-R-1 may be found at the following IAEA Web site: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1384_web.pdf.

These IAEA safety standards and regulations were developed in consultation with IAEA Member States, and 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 radioactive 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.

This rulemaking harmonizes the NRC's regulations with the IAEA's transportation regulations in TS-R-1 and aligns with the DOT regulations. The regulations in TS-R-1 represent an accepted set of requirements that provide a high level of safety in the packaging and transportation of radioactive materials and ~~provides for~~ 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.

In November 2012, the IAEA issued revised standards for the safe transport of radioactive material and designated them as "Specific Safety Requirements Number SSR-6" (SSR-6). The present NRC rulemaking does not incorporate the SSR-6 requirements, because

and A_2 values include contributions from daughter radionuclides with half-lives of less than 10 days. These additions conform to footnote a to Table 2, "Basic Radionuclide Values," in TS-R-1

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 but do not appear within Table A-1.

11. Footnote c to Table A-1 is moved to the A_1 values and revised to clarify that only the activity for iridium-192 (Ir-192) in special form may 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, the activity limit in Table A-2 for exempt consignment for tellurium-121m (Te-121m) is revised to be consistent with the new IAEA value in TS-R-1.

13. The list of parent radionuclides and their progeny included in secular equilibrium in footnote b to Table A-2 is revised to be consistent with the list accompanying Table 2 in TS-R-1.

14. The descriptive language in Table A-3, "General Values for A_1 and A_2 ," of appendix A under the heading "Contents" is revised to be consistent with the IAEA descriptions in Table 3, "Basic Radionuclide Values for Unknown Radionuclides or Mixtures," in TS-R-1(2009 edition). "Only alpha emitting nuclides are known to be present" is replaced with "Alpha emitting nuclides, but no neutron emitters, are known to be present." "No relevant data are available" is replaced with "Neutron emitting nuclides are known to be present or no relevant data are available." Additionally, footnote a is added to the new language "Alpha emitting nuclides, but no neutron emitters, are known to be present" stipulating that if beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 terabecquerel (TBq) (2.7 Ci) should be used.

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

The NRC is revising its 10 CFR 71.14(a)(1) exemption for natural materials and ores

The NRC is also revising the definition of LSA-I material in 10 CFR 71.4 (i.e., material intended to be processed for its radionuclides) so that it applies to uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides 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, will now apply to LSA-I material.

With the revision of the definition of LSA-I material, uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for these radionuclides may be able to qualify for the low-level material exemption in § 71.14(b)(3), provided that the other restrictions are satisfied. The restrictions include: 1) the package contains only LSA-I or Surface Contaminated Object (SCO)-I material or 2) ~~that~~ the LSA or SCO material has an external radiation dose rate of less than 10 millisieverts per hour (mSv/h) (1 rem per hour (rem/h)) at a distance of 3 meters from the unshielded material. Section 71.14 provides an exemption from the requirements of 10 CFR part 71, with the exception of §§ 71.5 and 71.88. Section 71.5 references the DOT's regulations in 49 CFR parts 107, 171 through 180, and 390 through 397. If the DOT's regulations are not applicable to a shipment of licensed material, then § 71.5 requires licensees to conform to the referenced DOT standards and regulations to the same extent as if the shipment were subject to the DOT's regulations. Section 71.88 will continue to apply to the material because its applicability is not limited by any of the exemptions in 10 CFR part 71.

Natural material or ore that has been incorporated into a manufactured product, such as an article, instrument, component of a manufactured article or instrument, or consumer item, will not qualify for the low-level material exemption for natural materials and ores containing naturally occurring radionuclides. Slags, sludges, tailings, residues, bag house dust, oil scale,

and washed sands that are the byproducts of processing or refining are examples that may contain natural material or ore that has been processed, are examples of material that may still qualify for the exemption, provided that the processed material has not been incorporated into a manufactured product.

The NRC is adding a definition for "contamination" to § 71.4 in conjunction with the new exemption in 10 CFR 71.14(a)(3) to include non-radioactive solid objects with substances present on any surface not exceeding the levels used to define contamination. Contamination is defined as quantities in excess of 0.4 Bq/cm^2 ($1 \times 10^{-5} \mu\text{Ci/cm}^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 ($1 \times 10^{-6} \mu\text{Ci/cm}^2$) for all other alpha emitters. The derived values used in the definition are conservative with respect to transportation. Quantities of radioactive substances below these values will result in small amounts of exposure during normal conditions of transportation and will contribute insignificant exposures under accident conditions.

E. How is the Qualification of Special Form Radioactive Material Changing?

The IAEA has incorporated in TS-R-1 the Class 4 and Class 5 impact tests in ISO 2919:1999(E), the Class 6 temperature test in ISO 2919:1999(E), and the leaktightness tests in ISO 9978:1992(E). The NRC is updating the alternate tests in § 71.75 that may be used for the qualification of special form radioactive material by incorporating by reference the Class 4 and Class 5 impact tests and the Class 6 temperature test prescribed in the ISO document ISO 2919:1999(E). The NRC is also incorporating by reference the leaktightness tests specified in ISO document 9978:1992(E).

The Class 4 impact test in ISO 2919:1999(E) replaces the impact test in § 71.75(d) and will be available for use with specimens that have a mass that is less than 200 grams. The Class 5 impact test, which is being added, will allow use of an ISO impact test for specimens

promulgate a rulemaking, the NRC should consider revising its proposed 10 CFR 71.14(a)(1) text to be consistent with the current SSR-6. Specifically, Section 107 of SSR-6 states that regulations do not apply to any of the following:

“(f) Natural material and ores containing naturally occurring radionuclides, which may have been processed, provided the activity concentration of the material does not exceed 10 times the values specified in Table 2, or calculated in accordance with paras 403(a) and 404–407. For natural materials and ores containing naturally occurring radionuclides that are not in secular equilibrium the calculation of the activity concentration shall be performed in accordance with para. 405.”

The commenter thus recommended revising the proposed 10 CFR 71.14(a)(1) provisions to exempt “Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have been processed, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Appendix A, Table A-2, or Table A-3, of this part.”

Response: The NRC is choosing not to make the commenter’s recommended revisions. The DOT/NRC MOU recognizes the DOT as the federal agency responsible for the definition of radioactive material in transit. After careful consideration, the DOT chose not to remove the intended use-clause in its current proposed rule, in part because the rule is intended to achieve compatibility with the 2009 Edition of the IAEA regulations, not the 2012 Edition. Publication of the 2012 Edition in October 2012, did not allow adequate time for the NRC and DOT to effectively evaluate the changes as part of this rulemaking effort. There are many other changes in the 2012 Edition that also are not reflected in either the proposed DOT or NRC rulemakings. ~~Changes in the DOT and NRC regulations to reflect the IAEA’s 2012 edition of SSR-6. The NRC will consider any necessary changes related to SSR-6 in a future rulemaking after consulting with the DOT, rather than further delay finalizing this rulemaking. will be addressed in subsequent rulemakings.~~ The NRC is choosing not to make such changes unilaterally, since doing so would create a conflict between DOT and

The definition of “Criticality Safety Index (CSI)” has been revised to be more consistent with the definition in the DOT’s regulations in 49 CFR 173 and TS-R-1 by addressing overpacks and freight containers in the definition.

The definition of “Low Specific Activity (LSA) material” has been revised so that it is more consistent with the definition in the DOT’s regulations in 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 that is intended to be processed for the use of the uranium, thorium, and other naturally occurring radionuclides. In paragraph (1)(ii), the definition is changed to clarify consideration of compounds or mixtures regardless of the form (solid or liquid.)

The definition of “Special form radioactive material” has been 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 [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. The reference to the version of 10 CFR part 71 in effect on March 31, 1996, is corrected by changing 1983 to 1996.

The definition of “Uranium—natural, depleted, enriched” has been revised by adding “(which may be chemically separated)” to paragraph (1), which applies to natural uranium.

Section 71.6 Information collection requirements: OMB approval.

Paragraph (b) is revised to add § 71.106 to the list of sections with information collections.

licensees to comply “with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H” of 10 CFR part 71. Because the quality

assurance provisions in subpart H for design, construction, and fabrication activities are not applicable to a general licensee, the exemption was ~~superfluous~~not needed.

Section 71.31 Contents of application.

In paragraph (b), the reference to § 71.13 is changed to § 71.19. This change was inadvertently omitted during a previous rulemaking, when certain sections were renumbered.

Section 71.38 Renewal of a certificate of compliance.

The title of this section is revised to remove the reference to the renewal of quality assurance program approvals. The section is revised to be limited to the renewal of CoCs by removing all references to quality assurance program approvals. The NRC is changing its practice regarding the duration of quality assurance program approvals. Quality assurance program approvals will not have an expiration date and the NRC will revise the current quality assurance program approvals so that they will not have an expiration date. The renewal of a quality assurance program approval is unnecessary. Paragraphs (a), (b) and (c) have also been revised for clarity.

Section 71.70 Incorporations by reference.

This section is added to incorporate by reference the consensus standards referenced in § 71.75: ISO 9978:1992(E), “Radiation protection—Sealed radioactive sources—Leakage test methods”; and ISO 2919:1999(E), “Radiation protection—Sealed radioactive sources—General

Section 71.85 Preliminary determinations.

In paragraphs (a), (b), and (c), “licensee” is replaced by “certificate holder.” The NRC experience is that these determinations are performed by the certificate holders who manufacture the package. This change will make the requirements consistent with current practice, because 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 address 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 are responsible for ensuring that these determinations have been made before their first use of the packaging.

Section 71.91 Records.

In paragraph(a), the reference to § 71.10 is changed to § 71.14. This reference was not updated when § 71.10 was redesignated as § 71.14.

Section 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 CoC are subject to the quality assurance requirements. Note that consistent with the existing 71.101(c)(1) QA-program-approval requirements 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) QA program approval requirements that are not being revised.~~

The provisions of 71.101(c)(2) are revised by removing the reference to licensees in the

will be required to identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change will continue to satisfy the requirements of subpart H of 10 CFR 71 that apply.

Paragraph (a)(2) will require that each holder of a quality assurance program approval maintain quality assurance program changes as records. These records will need to be maintained as required in § 71.135.

Paragraph (b) will allow the holder of a quality assurance program approval to make changes to its quality assurance program that will not reduce its commitments to the NRC and identify the changes that will not be considered as reducing its commitments to the NRC.

Paragraph (c) will require that records be maintained documenting any changes to the quality assurance program.

Section 71.135 Quality assurance records.

This section is revised to include those quality assurance records that apply to changes that are made to previously approved quality assurance programs. The second sentence is revised to include in the list of the types of records to be maintained the changes to the quality assurance program as required by new § 71.106.

Appendix A Determination of A_1 and A_2 .

In paragraphs IV.a. through IV.f., the equations and accompanying text are revised to make minor corrections. In paragraphs IV.a. and IV.b., the description of the equations will 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.

Current paragraphs IV.c. through IV.f. are redesignated as paragraphs IV.d. through

references the quality assurance programs for industrial radiographers is updated by changing § 71.12(b) to § 71.17(b).

XV. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC uses the consensus standards identified as follows and will incorporate them by reference. The NRC is adopting ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), for the Class 4 and Class 5 impact tests and the Class 6 temperature test; and ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), for the leaktightness tests.

In other portions of this final rule, the NRC is revising requirements that do not constitute the establishment of a standard that establishes generally applicable requirements. These revisions to the NRC's requirements include changes to: 1) the scope of material falling under an existing exemption for natural materials and ores containing naturally occurring radionuclides at an activity concentration below a specified value, 2) conditions on general licenses, 3) the oversight of quality assurance programs, and 4) the removal of transitional arrangements for previously approved packages.

and ore. The ~~preliminary~~ results and conclusions from the Coordinated Research Program are described in "~~Naturally Occurring Radioactive Material (NORM VI): Proceedings of an International Symposium, Marrakesh, Morocco, 22–26 March 2010, IAEA, 2011.~~ The ~~preliminary results of the Coordinated Research Program included: the IAEA published final report IAEA-TECDOC-1728, "Regulatory Control for the Safe Transport of Naturally Occurring Radioactive Material (NORM), Report of a Coordinated Research Project 2007–2010"~~ published in December 2013. At the time the proposed rule was published, the preliminary results of the Coordinated Research Program were available and included: (1) the most conservative scenario was the exposure to a truck driver and a factor of 15 could be used for the exemption of NORM materials for this scenario, even when there is no shielding between the driver and the radioactive load; (2) doses from exposure to released materials arising from potential accidents were less than 10 $\mu\text{Sv}/\text{year}$ (1 mrem/year) for the shipment of tantalum raw materials; (3) individual loads of some materials, depending on their composition (such as higher activities of radium), could lead to higher doses; and (4) doses to members of the public were at least an order of magnitude lower than for workers. The preliminary results of the Coordinated Research Program were generally consistent with allowing increased activity concentrations for naturally occurring material and ore containing naturally occurring radionuclides. ~~The final report published in 2013 confirmed these preliminary results. The recommendation of the final report was to propose a revision to IAEA regulations to apply the 10 times exemption value to all NORM materials.~~ Allowing activity concentration values of 10 times the exemption value will limit doses (from either single or multiple sources) so that they do not reach unacceptable levels and remain far below the public dose limits when considering both normal conditions and accident conditions.

In summary, the environmental impacts associated with the proposed changes to the low-level material exemption are expected to be small and not significant. Removing the

The Honorable Barbara Boxer
Chairman, Committee on Environment
and Public Works
United States Senate
Washington, DC 20510

Dear Madam Chairman:

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations related to the packaging and transportation of radioactive material. Some of the amendments have been made in consultation with the U.S. Department of Transportation (DOT), where the NRC is conforming its regulations to maintain consistency with the International Atomic Energy Agency's regulations regarding the international transportation of radioactive material. The DOT likewise amended its regulations in July 2014. The NRC final rule will soon be published in the *Federal Register*. The NRC's conforming amendments will become effective on July 13, 2015, which is the same date that the for mandatory compliance with DOT amendments, become effective. For more information, see the NRC's enclosed final rule.

Please feel free to contact me at (301) 415-1776 if you have questions or need more information.

Sincerely,

Eugene Dacus, Acting Director
Office of Congressional Affairs

Enclosure:
Federal Register notice

cc: Senator David Vitter