

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-A111

[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 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 material that qualifies for the fissile material exemption, clarify requirements, update administrative procedures, and make editorial changes.

DATES: Effective date: This rule is effective **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

Compliance date: Compliance with the amendments adopted in this final rule is required beginning July 13, 2015.

ADDRESSES: Please refer to Docket ID NRC-2008-0198 when contacting the NRC about the availability of information for this final rule. You may obtain publicly-available information related to this final rule by any of the following methods:

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0198. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this final rule.

- **NRC Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC PDR:** You may examine and purchase copies of public documents at the NRC PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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I. Background.

The NRC regulates the transportation of radioactive material under part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR). Periodically, the IAEA revises its regulations related to transportation of radioactive material. The NRC evaluated changes in the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1) and identified a number of areas in 10 CFR part 71 that needed to be revised to maintain compatibility with the IAEA's regulations. Accordingly, the NRC developed a proposed rule to amend 10 CFR part 71, and published it for comment in the *Federal Register* on May 16, 2013 (78 FR 28988).

The NRC is now publishing its final rule. Together with a related DOT final rule amending Title 49 of the *Code of Federal Regulations* (49 CFR) [79 FR 40590, July 11, 2014], these actions bring United States regulations into general accord with TS-R-1, and maintain consistency between NRC and DOT regulations. The NRC's final rule also revises 10 CFR part 71 to: 1) update administrative procedures for the quality assurance program requirements described in subpart H of 10 CFR part 71; 2) re-establish restrictions on material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary safety determinations on packaging to be used for transporting radioactive material; and 5) make editorial changes.

Compatibility with IAEA and Consistency with DOT Transportation Regulations

The IAEA was formed by member nations to promote safe, secure, and peaceful nuclear technologies. It establishes safety standards to protect public health and safety and to minimize the danger to life and property, and has developed safety standards for the safe transport of radioactive material in TS-R-1. Copies of TS-R-1 may be obtained from the United States

distributors, Bernan, 15200 NBN Way, P.O. Box 191, Blue Ridge Summit, PA 17214; telephone: 1-800-865-3457; e-mail: customercare@bernan.com, or Renouf Publishing Company Ltd., 812 Proctor Ave., Ogdensburg, NY 13669-2205; telephone: 1-888-551-7470; e-mail: orders@renoufbooks.com. An electronic copy 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

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 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.

Based on the public comments on the 1997 emergency final rule, the NRC contracted with the Oak Ridge National Laboratory (ORNL) to review the fissile material exemptions and general license provisions, study the regulatory and technical bases associated with these regulations, and perform criticality model calculations for different mixtures of fissile materials and moderators. The results of the ORNL study were documented in NUREG/CR-5342,¹ and the NRC published a notice of the availability of this document in the *Federal Register* (63 FR 44477; August 19, 1998). The ORNL study confirmed that the emergency final rule was needed to provide safe transportation of packages with special moderators that are shipped under the general license and fissile material exemptions, but concluded that the revised regulations may have been excessive for shipments where water moderation is the only concern. The ORNL study also recommended that the NRC revise 10 CFR part 71 as it applied to the requirement specific to uranium enriched in uranium-235 (U-235) to a maximum of 1 percent by weight, and with a total plutonium and uranium-233 (U-233) content of up to 1 percent of the mass of U-235. Specifically, as discussed in NUREG/CR-5342, ORNL recommended that 1) a definition of “homogeneity” be developed that could be clearly understood for use with uranium enriched to a maximum of 1 percent and 2) the term “lattice arrangement” be clarified or not used. Alternatively, ORNL suggested that the moderator criteria restricting the mass of beryllium, carbon, or heavy water (deuterium oxide) to less than 0.1 percent of the fissile mass should be maintained, which would remove the need to provide definitions such as “homogeneous” and “lattice arrangement” that are difficult to define and to apply practically.

The NRC chose to implement this ORNL suggestion, as reflected in a 2002 rulemaking regarding 10 CFR part 71 (67 FR 21390; April 30, 2002). Similar to the present rulemaking, the NRC in 2002 proposed to make the NRC’s regulations more consistent and compatible with

¹ NUREG/CR-5342, “Assessment and Recommendations for Fissile-Material Packaging Exemptions and General Licenses within 10 CFR Part 71,” July 1998, [ML12139A419](#).

IAEA's standards. Additionally, the NRC proposed to make changes to the fissile material exemption requirements to address the unintended economic impact of the 1997 final rule. In a final rule dated January 26, 2004 (69 FR 3698), the NRC removed the restriction (then stated in 10 CFR 71.53(b)) that, to qualify for the fissile material exemption, uranium enriched in U-235 must be distributed homogeneously throughout the package and may not form a lattice arrangement within the package. In addition, the 2004 final rule re-designated the section for fissile material exemptions from § 71.53 to § 71.15.

Although the NRC determined in 2004 that the limits on restricted moderators were sufficient to assure subcriticality for all moderators of concern, the NRC now believes that additional restrictions are needed to have a sufficient margin of criticality safety for shipments of material under the low-enriched fissile material exemption. Therefore, the NRC is revising 10 CFR 71.15(d) in this final rule by reinstating the requirement removed in 2004 that, for uranium enriched to a maximum of 1 percent to be exempted, the fissile material must be distributed homogeneously throughout the package contents and not form a lattice arrangement. Further technical details regarding the basis for now revising 10 CFR 71.15(d) are discussed in Section II.M of this document.

Quality Assurance Program Approvals

The regulations of part 71 require that licensees and certificate holders have quality assurance programs approved by the Commission as satisfying the applicable provisions of Subpart H of part 71. Unlike 10 CFR part 50, there are no specific requirements in part 71 addressing changes to an NRC-approved quality assurance program. Once a part 71 quality assurance program is approved, no changes to the program may be made without further NRC approval, because a change would alter the program and make it an unapproved program. Consequently, the process has been overly burdensome and inefficient for both the licensee

and the NRC. For example, under the existing part 71 requirements, a change in the quality assurance program to correct typographical errors or punctuation must be submitted to and approved by the NRC.

In 2004, the NRC changed the renewal period for quality assurance program approvals issued under 10 CFR part 71 from 5 years to 10 years in order to reduce the unnecessary regulatory burden of some administrative actions. This change was announced in “NRC Regulatory Information Summary (RIS) 2004-18, Expiration Date for 10 CFR Part 71 Quality Assurance Program Approvals,” dated December 1, 2004 (ADAMS Accession No. ML042160293).

Under the new 10 CFR 71.106, the NRC will allow some changes to be made to quality assurance programs previously approved under 10 CFR part 71 without obtaining additional NRC approval. The process for making changes to approved quality assurance program descriptions will now be similar to the process that the NRC has used to approve changes that are made to the quality assurance program descriptions for nuclear power plants licensed under 10 CFR part 50 through the provisions at § 50.54(a), and will result in a more consistent approach for allowing changes to approved quality assurance programs.

The NRC also will re-issue NRC Form 311 without an expiration date. The 24-month period for reporting changes will begin on the date of the NRC approval of a quality assurance program issued with no expiration date, as specified by the date of signature at the bottom of NRC Form 311. The changes being made to the quality assurance program approval process are discussed further in Sections II .H, II.I, and II.J of this document.

II. Discussion.

A. What Action is the NRC Taking?

The NRC is amending its regulations to make them more consistent and compatible with the IAEA's international transportation regulations TS-R-1. These revisions are also consistent with the DOT's hazardous materials regulations, and maintain a consistent framework for regulating the transportation and packaging of radioactive material.

In addition, the NRC is revising 10 CFR part 71 to: 1) update administrative procedures for the quality assurance program requirements described in subpart H of 10 CFR part 71; 2) re-establish criticality safety restrictions on certain material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and 5) make editorial changes.

B. Who is Affected by this Action?

This action affects: 1) NRC licensees authorized by a specific or general NRC license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, or transports the material outside of the site of usage as specified in the NRC license, or transports that material on public highways; 2) holders of, and applicants for a Certificate of Compliance (CoC); and 3) holders of a 10 CFR part 71, Subpart H quality assurance program approval. This action would also affect holders of quality assurance program approvals under Appendix B of part 50 or subpart G of part 72 to the extent that those approvals apply to transport packaging as specified in 10 CFR 71.101(f), "*Previously approved 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 NRC is correcting this so that LSA material includes material intended to be processed for its radionuclides.

4. The NRC is adopting the use of the Class 5 impact test prescribed in the International Organization for Standardization's (ISO) Document 2919, "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), ISO 2919:1999(E)², for special form radioactive material, provided the mass is less than 500 grams.

5. The NRC is incorporating by reference (A) ISO Document 2919, and (B) ISO Document 9978, "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), ISO 9978:1992(E).

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

7. The definition of "Special form radioactive material" in § 71.4 is revised to allow special form radioactive material that is successfully tested in accordance with the current requirements to be transported as special form radioactive material, if the testing was completed before the effective date of the final rule.

8. In Appendix A of 10 CFR part 71, Footnote h to californium-252 (Cf-252) (alternate A_1 and A_2 values for domestic use of Cf-252) in Table A-1, " A_1 and A_2 Values for Radionuclides," is eliminated. The A_1 and A_2 values in the table for Cf-252 are updated to be consistent with the IAEA values in TS-R-1.

9. Krypton-79 (Kr-79) values are added to Table A-1 and Table A-2, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides." The A_1 and A_2 values in Table A-1, the activity concentration for exempt material, and the activity limit for exempt consignment are consistent with the IAEA's values in TS-R-1.

10. Footnote a to Table A-1 is revised to include the list of parent radionuclides whose A_1

² (<http://pbadupws.nrc.gov/docs/ML0036/ML003686268.pdf>)

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 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 that exempts licensees from the requirements of 10 CFR part 71 for certain natural materials and ores. 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 allows the transport of 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 mSv/h (1 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/cm² (1x10⁻⁵ µCi/cm²) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² (1x10⁻⁶ µCi/cm²) 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

that have a mass that is less than 500 grams. The updated ISO impact tests maintain the requirement that the mass of the hammer used in the test is greater than 10 times the mass of the specimen.

The Class 6 temperature test in ISO 2919:1999(E) replaces the temperature test in § 71.75(d). The Class 6 temperature test in ISO 2919:1999(E) is more stringent than the test that it replaces because it requires the same specimen to be used for both portions of the temperature test. The Class 6 temperature test will continue to be more stringent than the testing required by § 71.75(b).

The leaktightness tests prescribed in ISO 9978:1992(E) replace the tests in ISO/TR 4826³. The consensus standard ISO 9978:1992(E) has replaced ISO/TR 4826:1979(E), which has been withdrawn by ISO. The NRC has determined that the leaktightness tests prescribed in ISO 9978:1992(E) provide an equivalent level of radiological safety as the leaching assessment procedure in § 71.75(c).

The NRC is revising the definition of “Special form radioactive material” in § 71.4 to allow material tested using the current requirements to continue to be treated as special form material, provided that the testing was completed before the effective date of the final rule. This will allow material tested using requirements in effect at the time of the testing to continue to be used. The NRC is revising the reference in § 71.4, which went into effect on March 31, 1996, by changing the date of the revision from January 1, 1983, to January 1, 1996.

The NRC is replacing “edges” with “edge” to describe the billet used for the percussion test in § 71.75(b)(2). The edge corresponds to the circular edge at the face of the billet. This revision clarifies the description of the billet and maintains consistency with the language used by the DOT in 49 CFR 173.469.

³ (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=10804)

F. What Changes are Being Made to 10 CFR part 71, Appendix A, “Determination of A₁ and A₂ Values”?

The NRC is changing the following items in appendix A:

1. Determination of the quantity of radioactive material that can be shipped in a package that contains both special form and normal form radioactive material.

The final rule specifically addresses how to calculate the limit of the activity that may be transported in a Type A package, if the package contains both special form and normal form radioactive material and the identities and activity limits for the radionuclides are known.

2. Table A-1, “A₁ and A₂ Values for Radionuclides.”

The values in Table A-1 have been revised to make the values in 10 CFR part 71 consistent with the values in Table 2, “Basic Radionuclide Values,” in TS-R-1. Specifically, the final rule: 1) adds an entry for Kr-79, which is now found in Table 2 in TS-R-1; 2) adopts the A₁ and A₂ values for Cf-252; 3) revises footnote a to include the list of parent radionuclides whose A₁ and A₂ values include contributions from daughter radionuclides with half-lives of less than 10 days; and 4) moves and revises footnote c, which formerly applied to all Ir-192, so that the footnote applies only to Ir-192 in special form material.

The IAEA added an entry for Kr-79 in Table 2 of TS-R-1. The NRC is adopting the same radionuclide-specific values for Kr-79 in Table A-1 in 10 CFR part 71. The radionuclide-specific values replace the generic values in Table A-3, which were previously used for Kr-79. The radiological criteria underlying the A₁ and A₂ values for Kr-79 have not changed, but the radionuclide-specific values were derived using radionuclide-specific information and better reflect the radiological hazard of Kr-79 than the generic values that they are replacing.

The IAEA revised the A₁ value for Cf-252 to the value that previously applied to domestic transportation. The NRC is adopting the A₁ value for Cf-252, which will apply to both

international and domestic transportation, and is adopting the IAEA value for A_2 . As a result, the final rule removes the A_2 value that formerly applied only to domestic transportation. Making this change improves the harmonization of 10 CFR part 71 with TS-R-1.

The final rule revises footnote a to Table A-1 that identifies the A_1 and A_2 values that include contributions from daughter radionuclides that have a half-life less than 10 days. The list corresponds to the radionuclides listed in footnote a to Table 2 in TS-R-1, with the exception of argon-42 (Ar-42) and tellurium-118 (Te-118). Argon-42 and Te-118 are not included because they do not appear within Table A-1 in 10 CFR part 71.

Footnote c to Table A-1 has been revised to clarify that the activity of 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 from the source.

3. Table A-2, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides."

The final rule revises Table A-2 to make the values in 10 CFR part 71 consistent with the values in TS-R-1 and adds an entry for Kr-79 adopted from Table 2 of TS-R-1. The final rule also updates the list of parent radionuclides and their progeny in footnote b to Table A-2 by removing the chains for the parent radionuclides cerium-134 (Ce-134), radon-220 (Rn-220), thorium-226 (Th-226), and U-240 and by adding the chain for the parent radionuclide silver-108m (Ag-108m) to make the footnote consistent with footnote (b) in Table 2 of TS-R-1. The activity limit for exempt consignment for Te-121m has also been updated to match the values in TS-R-1.

Materials that have an activity concentration that is less than the activity concentration for exempt material pose a very low radiological risk. The activity limit for exempt consignment has been established for the transportation of material in small quantities so that the total

activity is unlikely to result in any significant radiological exposure. This is the case, even for material that exceeds the activity concentration for exempt material.

Previously, Kr-79 was not listed in Table A-2 and instead values from Table A-3, “General Values for A₁ and A₂,” in appendix A were used to determine the activity concentration for exempt material and the activity limit for exempt consignment for Kr-79. Radionuclide-specific values for the activity concentration for exempt material and the activity limit for exempt consignment have been derived for Kr-79 and are now included in TS-R-1. The final rule adds an entry for Kr-79 to Table A-2 in 10 CFR part 71 to be consistent with TS-R-1.

In TS-R-1, the IAEA revised the activity limit for exempt consignment for Te-121m. The change to the activity level for exempt consignment for Te-121m, which is based on new analyses and information, is consistent with the objectives of the exemption values. To conform to International Commission on Radiological Protection (ICRP) and IAEA changes, the activity limit for exempt consignment for Te-121m in Table A-2 of 10 CFR part 71 is changed from 1×10^5 Bq (2.7×10^{-6} Ci) to 1×10^6 Bq (2.7×10^{-5} Ci).

The IAEA has revised the list of parent radionuclides and their progeny included in secular equilibrium in footnote (b) to Table 2 in TS-R-1. This revision arose from the adoption of the nuclide-specific basic radionuclide values from the Basic Safety Standards (IAEA Safety Series No. 115, “International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources” (1996)) for use in transportation. The list of parent radionuclides and their progeny was modified by adding the decay chain for Ag-108m and by removing the decay chains for Ce-134, Rn-220, Th-226, and U-240. The list of parent radionuclides and their progeny included in secular equilibrium presented in footnote b to Table A-2 is revised to be consistent with the changes to the list in TS-R-1.

4. Table A-3, "General Values for A_1 and A_2 ."

In the 2005 edition of TS-R-1, the IAEA revised Table 2, "Basic Radionuclide Values for unknown radionuclides or mixtures." The values are now in Table 3 in the 2009 edition of TS-R-1. The table divides unknown radionuclides and mixtures into three groups, with a row for each group. The first column of each row provides a descriptive phrase for contents that are suitable for that group. The NRC is adopting the new descriptive phrases in Table A-3 of 10 CFR part 71.

The descriptive phrase for the first group, "Only beta or gamma emitting radionuclides are known to be present," is not being changed. The phrase for the second group, "Only alpha emitting nuclides are known to be present," is being changed to "Alpha emitting nuclides, but no neutron emitters, are known to be present." The phrase for the third group, "No relevant data are available," is being changed to "Neutron emitting nuclides are known to be present or no relevant data are available."

Some users have assigned alpha-emitting radionuclides that also emit beta particles or gamma rays to the third group, when it was intended that they be assigned to the second group. The change in the descriptive phrase for the second group is intended to reduce the confusion caused by the current phrase because all alpha emitting radionuclides also emit other particles and/or gamma rays. The change in the descriptive phrase for the third group is intended to clarify that neutron-emitting radionuclides, or alpha emitters that also emit neutrons, such as Cf-252, Cf-254 and curium-248 (Cm-248), should be assigned to the third group.

It is intended that when groups of radionuclides are based on the total alpha activity and the total beta and gamma activity, the lowest radionuclide values (A_1 or A_2) for the alpha emitters or the beta or gamma emitters, respectively, are used. Consequently, an A_1 value of

1 TBq (2.7 Ci) and an A_2 value of 9×10^{-5} TBq (2.4×10^{-3} Ci) are used for a group containing both alpha emitting radionuclides and beta or gamma emitting radionuclides.

5. Other changes that correct formulas and their descriptions in section IV of appendix A.

The NRC is making several corrections to the formulas and the descriptions of the formulas that address mixtures of radionuclides in section IV of appendix A in 10 CFR part 71. These changes involve formatting and typographical changes in the formulas and their descriptions.

G. How Will the Responsibilities of Certificate Holders and Licensees Change with these Amendments?

The final rule revises § 71.85(a)-(c) to make certificate holders, not licensees, responsible for making the required preliminary determinations before the first use of any package for shipping radioactive material. The preliminary determinations involve evaluating, testing, and marking the packaging. The DOT's requirements in 49 CFR 173.22 require that the person offering a hazardous material for shipping make determinations relating to the manufacturing, assembly, and marking of the packaging or container. New § 71.85(d) will require licensees to ascertain that the certificate holders have made the required preliminary determinations. Note that before each shipment, licensees must still make the findings required by the existing § 71.87(a)-(k) provisions, to ensure the continued safety of packages containing radioactive material.

The NRC is revising § 71.85, because it is more appropriate to assign the responsibility to certificate holders for evaluating, testing, and marking the packaging. Only certificate holders are authorized to design and fabricate packages, and only certificate holders have a full scope

quality assurance program approval. By assigning the responsibility for making the preliminary determinations to the certificate holder, the NRC streamlines the implementation of its regulations, and the revisions to § 71.85 also better reflect current practice.

Reflecting the revisions to § 71.85(a)-(c) previously discussed, conforming changes are made to the § 71.101 Quality Assurance (QA) provisions, to clarify that only certificate holders and applicants for a CoC have QA responsibilities regarding the fabrication and testing of packages. In this regard, references to licensees §§ 71.101(a) and (c)(2) have been removed.

H. Why is Renewal of My Quality Assurance Program Description not Necessary?

The duration of quality assurance program approvals issued under 10 CFR part 71 is a matter of practice and is not specified in the regulations. The NRC has limited the duration of the quality assurance program approval by assigning an expiration date to NRC Form 311, “Quality Assurance Program Approval for Radioactive Material Packages.” The inclusion of an expiration date provided an opportunity for the NRC to periodically review the quality assurance programs and for the NRC to maintain periodic contact with the quality assurance program approval holders.

The NRC is changing its practice regarding the duration of its quality assurance program approvals. The NRC will no longer limit the duration of its quality assurance program approvals issued under 10 CFR part 71. The NRC is amending 10 CFR part 71 to implement this change in order to make the periodic communication between the NRC and the quality assurance program approval holders more efficient. The NRC will reissue NRC Form 311 without an expiration date.

The NRC is still requiring quality assurance program approval holders to periodically report changes in their quality assurance program description to the NRC. However, the NRC

has determined that with the continuing contact between the NRC and the quality assurance program approval holders, requiring the renewal of quality assurance program approvals is no longer necessary. Every 24 months, each quality assurance program approval holder is required to report those changes that do not reduce commitments made to the NRC in a quality assurance program description. Regarding quality assurance program description changes that reduce commitments made to the NRC, such changes will continue to require NRC approval.

The NRC expects that this new process will provide the NRC with adequate assurance that the quality assurance program approval holders will continue to maintain and implement their approved quality assurance programs, while reducing regulatory burden and the expenditure of NRC resources.

I. What Changes Can be Made to a Quality Assurance Program Description without Seeking Prior NRC Approval?

Previously, quality assurance program descriptions approved under 10 CFR part 71 could not be changed without NRC approval. Therefore, all changes to 10 CFR part 71 quality assurance programs, irrespective of their significance or importance to safety, were required to be submitted to the NRC for approval. Licensees with quality assurance programs approved under 10 CFR part 50, may make some changes to their quality assurance program without NRC approval, in accordance with 10 CFR 50.54. Under the final rule, the NRC will allow some changes to be made to quality assurance programs previously approved under 10 CFR part 71 without obtaining additional NRC approval. As indicated previously, the new process for making changes to approved quality assurance program descriptions under 10 CFR part 71 will be similar to the process that the NRC has used to approve changes that are made to the quality assurance program descriptions for nuclear power plants and will result in a more consistent

NRC-wide approach. As stated previously in II.H, quality assurance program description changes that reduce commitments made to the NRC will continue to require NRC approval. For such changes, the following information will need to be provided for NRC review: a description of the proposed changes, the reason for the changes, and the basis for concluding that the revised program incorporating the changes will continue to satisfy the requirements of 10 CFR part 71 subpart H.

Quality assurance program approval holders will no longer be required to submit for NRC approval changes to their quality assurance program descriptions under part 71, if those changes do not reduce the commitments that they have made to the NRC. For example, administrative changes (e.g., revisions to format, font size or style, paper size for drawings and graphics, or revised paper color) and clarifications, spelling corrections, and non-substantive editorial or punctuation changes will not require NRC approval. Five types of non-substantive changes that will no longer require NRC approval are being codified in the new 10 CFR 71.106(b) provisions. Changes to reporting responsibilities, functional responsibilities, and functional relationships may be substantive and have the potential to reduce commitments made to the NRC. Such changes will thus still require prior NRC approval before being implemented, and quality assurance program approval holders will still be required to maintain records of all quality assurance program changes.

J. How Frequently do I Submit Periodic Updates on My Quality Assurance Program Description to the NRC?

Under the revised requirements, every 24 months, quality assurance program approval holders will be required to report changes to their approved quality assurance program that do not reduce any commitments in their quality assurance program descriptions. Such changes

will no longer require NRC approval before they can be implemented. If a quality assurance program approval holder has not made any changes to its approved quality assurance program description during the preceding 24-month period, the approval holder will be required to report this to the NRC.

The NRC inspection program relies on having current information about the quality assurance program available to the NRC. By requiring that the most important changes be submitted to the NRC for approval before they are implemented, and with the periodic reporting of non-substantive changes every 24 months, the NRC will have current information for its inspection program. The NRC considers the 24-month reporting period as providing an appropriate balance between the burden placed on the quality assurance program approval holders and the need to ensure that the NRC has current information for its oversight of these quality assurance programs.

As previously stated in Section I, the NRC will re-issue NRC Form 311 without an expiration date. The 24-month period for reporting of changes will begin on the date of the NRC approval of a quality assurance program issued with no expiration date, as specified by the date of signature at the bottom of NRC Form 311. By making these changes, the NRC is seeking to balance the regulatory burden for submitting and reviewing this information with the NRC's need to ensure that the NRC has current information.

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 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 packaging, and the actions that are to be taken before shipment with the package. The changes also clarify that the notifications to the NRC, as required in § 71.17(c)(3), are a responsibility of the licensee, rather than a condition for obtaining the license. The changes to §§ 71.17 and 71.21 do not change the current notification process nor the required timing or content of the notification required by

§ 71.17(c)(3) or any other reporting requirements relating to package use or, when required, the prior notification of shipments.

The changes also update the reference in § 71.21(a) from 49 CFR 171.12 to 49 CFR 171.23 to reflect a DOT final rule published on May 3, 2007 (72 FR 25162) that previously moved the requirements.

M. How is the Exemption from Classification as Fissile Material (10 CFR 71.15) Changing?

The NRC is revising § 71.15(d) criteria that, if satisfied, exempt certain material from being classified as fissile material. Material within the scope of § 71.15 is exempt from the fissile material package standards and criticality safety requirements stated in §§ 71.55 and 71.59.

The objective of the fissile material exemptions in § 71.15 is to facilitate the safe transport of low-risk (e.g., small quantities or low concentrations) fissile material. This is done by exempting shipments of these materials from the packaging requirements and the criticality safety assessments required for fissile material transportation so that the shipments may take place without specific NRC approval. A lower amount of regulatory oversight is acceptable for these shipments because the exemptions were established to ensure safety under all credible transportation conditions. Provided that the exempt material is packaged consistent with the radioactive and hazardous properties of the material, there are no additional packaging or transport requirements for exempt fissile material beyond those noted in the specific exemption. 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 homogeneous 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 critical enrichment is lower for an optimized heterogeneous system than for an optimized

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).

homogeneous system of the same material. In consideration of this fact, requirements have been added to § 71.15(d) in order to clarify the need for homogeneity in the material.

The exemption for uranium enriched to a maximum of 1 percent at § 71.15(d) includes a limit on moderators that increases the reactivity of the low-enriched fissile material, but it does not include limits on heterogeneity. In contrast, TS-R-1 allows the uranium enriched to a maximum of 1 percent by weight to be distributed essentially homogeneously throughout the material and requires that if the U-235 is in metallic, oxide, or carbide forms then it cannot form a lattice arrangement, but TS-R-1 does not limit the amount of beryllium, graphite, or hydrogenous material enriched in deuterium. In its supplemental guidance to TS-R-1, TS-G-1.1 “Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material,”⁵ the IAEA indicated that “[t]here is agreement that homogeneous mixtures and slurries are those in which the particles in the mixture are uniformly distributed and have a diameter no larger than 127 μm [(5 $\times 10^{-3}$ in.)].” The homogeneity requirement in TS-R-1 is intended to prevent latticing of slightly enriched uranium in a moderating medium.

An analysis performed by the DOE indicated that large arrays of uranium with enrichment of 1 percent by weight of U-235, which qualify for the fissile material exemption at § 71.15(d), could exceed an effective neutron multiplication factor (k_{eff}) of 0.95 when optimally moderated by water. The DOE analysis was performed assuming five shipments under normal conditions and two shipments under accident conditions. Shipping the material under the exemption would have resulted in a lower margin of safety with respect to criticality than is allowed for shipments using approved fissile material packages, because shipments using the fissile material packages, by design, will typically use a k_{eff} of 0.95 as an upper limit. Because such a shipment, as was analyzed by the DOE, could both qualify for the fissile material

⁵ http://www-pub.iaea.org/MTCD/publications/PDF/Pub1109_scr.pdf

exemption for low-enriched fissile material and have a k_{eff} greater than 0.95, the NRC believes that additional restrictions on low-enriched fissile material shipped under the fissile material exemption in § 71.15(d) are warranted.

As discussed in Section I of this document, the NRC in 2004 removed exemption provisions regarding homogeneous distribution and lattice arrangement. Although the NRC had determined that the limits on restricted moderators were sufficient to assure subcriticality for all moderators of concern, the NRC now believes that additional restrictions are needed to have a sufficient margin of safety for shipments of material under the low-enriched fissile material exemption. Therefore, the NRC is reinstating the requirement that, for uranium enriched to a maximum of 1 percent to be exempted, the fissile material must be distributed homogeneously throughout the package contents and not form a lattice arrangement. Some variability in the distribution and enrichment of the uranium enriched to a maximum of 1 percent is permissible, provided that the maximum enrichment does not exceed 1 percent. The total measured mass of U-233 and plutonium, plus two times the measurement uncertainty, must be less than 1.0 percent of the mass of U-235 in the material. The total measured mass of beryllium, graphite, and hydrogenous material enriched in deuterium, plus two times the measurement uncertainty, must be less than 5.0 percent of the uranium mass. Although there are heterogeneity effects at very small scales, the NRC does not believe that it is necessary to require homogeneity with respect to particle size. Further, the NRC does not consider it to be credible to accumulate the volume and regularity of fissile material particles necessary for small-scale heterogeneity to introduce criticality concerns. Small volumes of heterogeneity may exist for material shipped under this exemption, provided that a significant fraction of the fissile material is homogeneous and mixed with non-fissile material, or the lumps of fissile material are spaced in a largely irregular arrangement. The homogeneity criterion, allowing some variability in the distribution of

fissile material, is consistent with the IAEA's regulations, which require that the fissile nuclides be essentially homogeneously distributed. Restricting the variability in concentration is not sufficient for limiting the reactivity of the uranium enriched to a maximum of 1 percent; therefore, the NRC is reinstating the lattice prevention criterion. The contents of the package must not involve concentrations of fissile material separated by non-fissile material in a regular, lattice-like arrangement. Although the lattice prevention requirement in TS-R-1 is limited to uranium present in metallic, oxide, or carbide form, the NRC believes that this restriction is too narrow and should apply irrespective of the form of uranium.

N. What Other Changes is the NRC Making to its Regulations for the Packaging and Transportation of Radioactive Material?

A requirement in § 71.19(a) that implemented transitional arrangements ("grandfathering") expired on October 1, 2008, and § 71.19(a) was designated as "reserved." Because this entry is no longer needed, paragraphs (b) through (e) have been redesignated as paragraphs (a) through (d). In the redesignated paragraph (b)(2), transitional language that is no longer needed has been removed because the transitional period has expired and the requirement now applies to all previously approved packages used for a shipment to a location outside of the United States.

The reference to § 71.20 in § 71.0 has been removed, because § 71.20 has expired and is no longer included in the regulations.

In § 71.31, the reference to § 71.13 has been changed to § 71.19. In § 71.91, the reference to § 71.10 has been changed to § 71.14. These changes will correct references that were not updated when the requirements were redesignated in 2004.

O. When do These Proposed Amendments Become Effective?

This rule is effective **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Compliance with the amendments adopted in this final rule is required beginning July 13, 2015. Agreement States, under their formal agreements with the NRC, have 3 years after the effective date of the rule to adopt the changes.

III. Opportunities for Public Participation.

The proposed rule was published on May 16, 2013 (78 FR 28988), for a 75-day public comment period that ended on July 30, 2013. The NRC received eight comments from Federal agencies, States, licensees, industry organizations, and individuals. Copies of the public comments are available in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852; or at <http://www.regulations.gov> under Docket ID NRC-2008-0198.

IV. Public Comment Analysis.

In general, there was a range of stakeholder views concerning the proposed rule. Two commenters voiced general support of the NRC's efforts to harmonize 10 CFR part 71 with the DOT's and the IAEA's regulations. Three other commenters indicated support for the proposed revisions to the definition of LSA group I, with two of those commenters stating their view that this proposed revision corrected a longstanding error in the NRC's regulations that created an incompatibility with existing DOT regulations. Other commenters voiced general support for the proposed revisions to quality assurance requirements and for provisions related to exempted low-level material. The comments and responses have been grouped into five topical areas:

New and Revised Definitions, Exemptions for Low-level Materials, Quality Assurance, Technical Requirements, and Other. To the extent possible, all of the comments on a particular subject are grouped together.

The NRC specifically requested input on three subjects: 1) frequency for reporting changes to an approved quality assurance program; 2) clarity of new restrictions on low-enriched fissile material in § 71.15(d); and 3) the cumulative effects of this rulemaking, including influence of other regulatory actions, unintended consequences, and reasonableness of the cost benefit estimates. These subjects are addressed within the appropriate area grouping. A discussion summarizing the comments and providing the NRC's comment responses follows. The NRC finds that the comments did not require any changes to the proposed rule's provisions.

A. New and Revised Definitions

A.1 Contamination

Comment: One commenter was concerned that DOT had stated in its parallel proposed rule *Federal Register* notice that the DOT did not have the regulatory authority to establish a radioactive material unrestricted transfer (free release) limit and was leaving it to the NRC as to whether the NRC would continue a longstanding provision of the DOT's regulations that allowed conveyances that meet the return to service (RTS) standards to be released without applying NRC licensing requirements. The commenter stated that with the DOT and the NRC adopting the same definition of "*contamination*," and excluding conveyances with contamination below the limits established by that definition, it was the commenter's view that the transportation requirements of the DOT and the NRC are not applicable to such conveyances. It was also the commenter's view that by adopting the

DOT's definition for *contamination*, the NRC is continuing the long-held position that, for materials below the level that meet the definition of contamination for conveyances in transportation or storage incidental to transportation, conveyances in transportation do not need to be licensed.

Response: The NRC does not agree with the commenter's views, because they are contrary to existing general provisions in part 71. Specifically, 10 CFR 71.0(b) states that the part 71 requirements "are in addition to, and not in substitution for," NRC requirements in other 10 CFR parts. Additionally, existing 10 CFR 71.0(c) states that no provision in part 71 "authorizes possession of licensed material." Thus, the new definition of *contamination* in § 71.4, and the new exemption for contamination in § 71.14 (a)(3) applicable to transport of material, are sufficiently clear, and should not be misconstrued as providing relief from the provisions of any other applicable parts of 10 CFR, in particular with respect to the licensing of on-site materials, (also see response to comment D.4.).

Comment: One commenter stated that although the application of the definition of contamination provides a regulatory path for the release of conveyances, the current language found in 49 CFR 173.443(c) and the associated table of contamination limits should be incorporated into the NRC's regulations as an authorized method to remove conveyances from licensed control when the conveyances are limited to the transportation of contaminated or potentially contaminated material or storage for future such transportation.

Response: The comment does not provide a sufficient basis to incorporate this DOT regulation into NRC's regulations. The DOT and the NRC share regulatory responsibility for the safety of radioactive materials in transport. To avoid duplication of effort and imposing unnecessary burden, the respective roles of the two agencies are delineated in the DOT/NRC MOU. Under this MOU, the NRC recognizes the DOT's authority to define and

regulate the safety of Class 7 Hazardous Materials (radioactive materials) in transport. The NRC requires its licensees to comply with the DOT's regulations when transporting radioactive materials. The DOT has issued regulations for safe transport of radioactive materials by all modes, including requirements addressing residual contamination on conveyances, and the NRC believes the DOT regulations regarding contaminated conveyances are adequate to protect public health and safety. Accordingly, the NRC sees no need to duplicate the DOT's conveyance provisions in 10 CFR. Note also that the NRC issues licenses to persons to possess, use, and transfer radioactive materials; the NRC does not license conveyances.

Comment: One commenter stated that the NRC, by defining contamination, is establishing a de minimis quantity. The commenter believed that this is a sensible view given the minimal potential for contamination in transportation or storage pending future transportation and that this approach constitutes a sound application of the NRC's risk-informed, performance-based approach. The commenter indicated, however, that it would be helpful, given the many stakeholders and Agreement State regulators, that this position be clearly stated in the NRC's regulations. Specifically, the commenter recommended that the proposed § 71.14(a)(3) exemption be modified (as indicated by the underlined text) to state: "(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in § 71.4 of this part. Such objects in the transportation process, or in storage pending future transportation, 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*, another commenter was concerned that the new language being added to its revised paragraph (3), "... 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 radionuclides.

Response: The comment does not specify the exemption provisions that are of concern, but as indicated in this response, the NRC assumes that those in 10 CFR 71.14 are at issue. The NRC does not find there is any discrepancy between the revised 71.14(a)(1)

exemption, and the existing 71.14(b)(3)(ii) exemption that is not being revised. The NRC is revising the 10 CFR 71.14(a)(1) exemption to include natural material and ores containing naturally occurring radionuclides that—1) are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and 2) are not intended to be processed for the use of these radionuclides, provided that they do not exceed 10 times the activity concentration values listed in Table A-2 or Table A-3, as appropriate. 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, would be within the scope of this revised exemption. A licensee is exempt from all the requirements of Part 71 with respect to shipment or carriage of this material.

The NRC is also revising the definition of LSA-I in 10 CFR 71.4 to include uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of radioactive materials. Under existing 71.14(b)(3)(ii), a licensee is exempt from all the requirements of part 71, other than §§ 71.5 and 71.88, with respect to shipment or carriage of packages containing LSA-I, provided the packages do not contain any fissile material, or the material is exempt from classification as fissile material under § 71.15. As revised, the NRC finds that the definition of LSA-I is adequate to ensure that material is properly characterized; 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 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 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 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 recommended need to have affected individuals instructed on the revised QA program before the changes are implemented, existing § 71.105(d) states in relevant part that a licensee or CoC

holder “shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.” The NRC finds that this existing requirement adequately ensures that affected individuals will be properly instructed before any QA program changes are implemented.

Regarding the third recommendation to have records of these instructions created and maintained, the NRC finds that this addition to proposed 10 CFR 71.106 is not necessary, because it is adequately addressed by the existing criteria stated in § 71.135 (“Quality assurance records”). Specifically, § 71.135 states in relevant part that a licensee or CoC holder must maintain written records, and that such records include instructions pertaining to the “required qualifications of personnel.” The NRC finds that this existing requirement adequately ensures that training records will be created and maintained.

Comment: Regarding proposed 10 CFR 71.106, a commenter requested that corresponding changes be made to 10 CFR part 72, Subpart G. The commenter recommended that the NRC initiate action to make similar and compatible changes to 10 CFR 72 subpart G, so that all QA program changes that do not reduce commitments could be implemented without prior NRC approval.

Response: The NRC agrees with the commenter’s recommendation, and will consider making the recommended changes to 10 CFR part 72 during a future rulemaking. However, changes to 10 CFR part 72 are outside the scope of this part 71 rulemaking. Note that existing sets of parallel QA provisions in 10 CFR 71.101(f) and 10 CFR 72.140(d) allow for a single QA program to meet both the requirements of 10 CFR part 71 and 10 CFR part 72.

D. Technical Requirements

D.1 Latticing/Homogeneity

Comment: One commenter recommended that clarifying language be provided relating to the prevention of latticing and also homogeneity as it relates to the exemption for uranium enriched up to 1 percent. The commenter noted that similar language to the proposed language existed in earlier versions of the regulations, and that NUREG/CR 5342 recommended that the terms “lattice arrangement” and “homogeneity” either be removed or defined.

Response: The intent of the fissile material exemptions in 10 CFR 71.15 is to facilitate the safe transport of small quantities or low concentrations of fissile material. This is accomplished by exempting such fissile material from the criticality safety requirements in 10 CFR 71.55 and 71.59 that are generally applicable to fissile material transportation packages. Since these packaging requirements are not applicable pursuant to the 10 CFR 71.15 exemptions, it is conservatively assumed that a) small quantities or low concentrations of fissile material can be released from packaging during transport, b) this material may configure into a worst-case geometric arrangement, and c) the fissile material may be subject to the fire and water immersion conditions assumed for transportation criticality analyses performed for approved packages under 10 CFR 71.55. The 10 CFR 71.15 exemptions are intended to ensure that criticality safety is maintained under all credible transportation conditions, although it is recognized that unlikely scenarios may be conceived which can make almost any amount or concentration of material become a criticality safety concern. As indicated in the comment, the NRC is restoring former lattice arrangement and homogeneous distribution provisions, as discussed in the following section, regarding the revised 10 CFR 71.15(d) exemption requirement.

Uranium enriched to less than 5.0 weight percent U-235 is generally more reactive in a heterogeneous configuration than when it is distributed homogeneously within a transportation package. The fissile exemption for uranium enriched to a maximum of 1.0 weight percent U-235 in 10 CFR 71.15(d) is based on the fact that this enrichment level is slightly less than the minimum critical U-235 enrichment for infinite homogeneous mixtures of uranium and water. Accordingly, 10 CFR 71.15(d) as revised requires that the fissile material be distributed homogeneously within its transportation package, and excludes from the exemption's scope situations where fissile "lumps" or lattice arrangements of fissile material are present within the package. The 10 CFR 71.15(d) exemption language continues to exclude large quantities (less than 5 percent of the uranium mass) of low-absorbing moderators (beryllium, graphite, or hydrogenous material enriched in deuterium). These requirements will preclude fissile material arrangements in packages that can potentially result in criticality at U-235 enrichments less than 1 weight percent.

Homogeneity and lattice arrangement are well understood terms in the criticality safety community. *Nuclear Criticality Safety—Theory and Practice* (Knief, 1998), states that heterogeneous systems are generally defined as any mixtures of fissile and moderator materials with uniformly distributed fissile material particles larger than ~0.1 mm. Additionally, the IAEA Safety Guide TS-G-1.1, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, contains a description of essentially homogeneous materials as "those in which the particles in the mixture are uniformly distributed and have a diameter no larger than 127 microns (0.127 mm)." Lattice arrangement means a fixed, repeating configuration of separate fissile material lumps. A nuclear fuel assembly is an example of a lattice arrangement.

For the exemption in 10 CFR 71.15(d), small volumes of heterogeneity may exist, provided that a significant fraction of fissile material is homogeneous and mixed with non-fissile

material, or lumps of fissile material are in a largely irregular arrangement. Further, heterogeneous effects in a package due to large fissile material lumps/particles or lattice arrangements of fissile material would only affect criticality safety in a regular or near-optimal configuration over a large volume. Large quantities of fissile material (kilograms of U-235) and regions of heterogeneity on the order of a cubic meter in size are necessary before a system could adversely affect the validity of the 1 weight percent U-235 enrichment limit for this fissile exemption.

D.2 Container Closure Verification

Comment: One commenter was concerned that requiring the closure of waste containers be verified by two independent inspectors prior to shipment in a licensed package was not risk-informed. The commenter believed that this new requirement was based on an incident with an iridium source. The commenter stated that the majority of low-level radioactive waste (LLRW) containers transported in licensed packages are LSA group II materials that exhibit a few areas of elevated dose rates that can exceed 1 R/hr at 3 meters and that this dose rate limit is the main reason licensed shipping packages are employed for transport of large containers of commercial LLRW in the United States. The commenter believes that the risk from LSA material does not warrant the dual container closure independent inspection requirement and that such requirements should be limited to concentrated radioactive sources similar to the one involved in the incident with an iridium source.

Response: The NRC's proposed rule did not address this topic. The NRC neither has at present, nor is it proposing, a requirement that "waste containers be verified by two 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 LSA II (ii). The proposed change regarding iridium pertains only to the placement of an explanatory footnote in part 71 Appendix A, Table A-1, to make clear that the activity of special

form iridium sources may be determined through measurement at a prescribed distance from the source.

Comment: A commenter stated that the NRC is now requiring registered users of licensed packages to conduct and provide radiolysis calculations on hydrogen gas generation. The commenter does not believe a requirement for such calculations is risk informed. Combustible Gas generation within a licensed transport package is a valid concern. According to the commenter, based on past history, the source of combustible gas generation from commercial LLRW is not from radiolysis, but rather from biological sources (methane) or rusting of waste container internals (hydrogen) noted as bulging drums. The commenter is not aware of any calculation method for biological or rusting combustible gas generation.

Response: This comment does not provide sufficient technical basis for evaluation. The NRC is not aware of any requirement that registered users of licensed packages conduct and provide radiolysis calculations on hydrogen gas generation. Nor is the NRC aware of any history showing that commercial LLRW is generating combustible gas from either biological sources (methane) or rusting of waste container internals. The topics discussed in this comment are outside the scope of this rulemaking.

D.4 Storage of Radioactive Material Containers

Comment: One commenter had concerns that the proposed revision to the DOT's and the NRC's regulations may have the unintended consequence of severely complicating the storage of radioactive material containers and conveyances when they are not in use. The DOT's rule essentially defines "returned to service (RTS)" conveyances not in use for Class 7 material as radioactive material; therefore, it implies that a radioactive material license is necessary to store these RTS conveyances when they are not transporting Class 7 material.

The commenter is concerned that this would impose a significant burden on industry processors as there are no licensed facilities that have sufficient capacity to store the inventory of gondola rail cars and other conveyances. The commenter does not believe that the DOT has demonstrated, nor that in fact there exists, a health and safety justification for imposing new restrictions on the storage of conveyances while not in use. The commenter recommends that the NRC should amend § 71.14(a) to add a paragraph 4 that would read as follows: “(4) Transport vehicles with radioactive substances meeting the return to service provisions of 49 CFR 173.443(c) in effect on September 13, 2004, when in transport of contaminated or potentially contaminated material or empty vehicles in storage pending future such transportation. Such vehicles need not be licensed under this chapter.”

Response: The NRC disagrees with this comment, because adding the requested exemption to § 71.14(a) would be contrary to existing general provisions in part 71. Specifically, 10 CFR 71.0(b) states that the part 71 requirements “are in addition to, and not in substitution for,” NRC requirements in other 10 CFR parts. Also, existing 10 CFR 71.0(c) states that no provision in part 71 “authorizes possession of licensed material.” The suggestion that NRC use its part 71 transport regulations to exempt certain transport vehicles from the need to have an NRC license is thus not permissible. Furthermore, under the DOT/NRC MOU, the DOT is responsible for regulation of Class 7 (radioactive) material in transport. The DOT is responsible for all transport modes, including highway and railway conveyances. The DOT has established radiation dose rate and removable contamination levels for returning exclusive use vehicles to service. However, allowing exemption or release from licensing of radioactive material, including conveyances not in service, at these levels would not be compatible with current and generally accepted radiation protection practices, (also see response to comment A.1).

E. Other

E.1 Agreement State Compatibility

Comment: One commenter recommended that the compatibility for the new proposed 10 CFR 71.85(d) be changed to 'NRC' since paragraphs (a) through (c) are being revised to compatibility "NRC."

Response: The NRC disagrees with this comment. As stated in the 2013 statement of considerations in the *Federal Register* notice of the proposed rule, paragraphs (a) through (c) of § 71.85 would be designated as Compatibility Category NRC because as revised they would apply exclusively to certificate holders, and granting package approvals to certificate holders is an action reserved to the NRC. New § 71.85(d) applies to NRC licensees and licensees in Agreement States that use the packages. This new requirement has been designated as Compatibility Category "B" because it applies to activities that have direct and significant effects in multiple jurisdictions, and Agreement States should adopt program elements essentially identical to those of NRC to achieve nationwide consistency.

Comment: One commenter recommended that the Agreement States be offered 3 years to implement these changes when they are finalized by the NRC.

Response: Agreement States, under their formal agreements with the NRC, have 3 years after the effective date of the rule to adopt the changes.

E.2 Cumulative Effect of Regulation

Comment: Section III.P of the *Federal Register* notice for the proposed rule asked, "Do other regulatory actions influence the implementation of the proposed requirements?" One commenter answered "yes" to this question and stated that the creation of 10 CFR part 37 and the revisions of 10 CFR parts 35 and 61 should take precedence over this 10 CFR part 71

revision. The commenter indicated this revision would also add to the workload of Agreement State staff needing to revise their applicable regulations.

Response: The NRC agrees with the commenter that implementation of this rulemaking will impact the Agreement States that are currently implementing changes related to the recent promulgation of other rule changes such as 10 CFR part 37. However, these 10 CFR part 71 amendments are necessary to make the NRC's regulations conform to the IAEA's regulations for the international transportation of radioactive material, and to maintain consistency with the DOT's regulations. Agreement States may, and often do, combine the action of making their regulations compatible with multiple NRC rule changes in one State rulemaking action, which can somewhat reduce overall effort. Regarding the added burden that may result from future changes to 10 CFR parts 35 and 61, it is uncertain when the final rule changes for those parts may be approved by the Commission and promulgated.

V. Section-by-Section Analysis.

Section 71.0 Purpose and scope.

Paragraph (d)(1) has been revised to delete § 71.20 from the list of sections in which a general license is issued without requiring the NRC to issue a package approval. The list of sections has been revised to add §§ 71.21 through 71.23.

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.

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.

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 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.

Section 71.15 Exemption from classification as fissile material.

Paragraph (d), which applies to fissile material in the form of uranium enriched in U-235 to a maximum of 1 percent by weight, has been revised. To qualify under the revised

exemption, the fissile material will need to be distributed homogeneously and not form a lattice arrangement within the package. The revision re-establishes restrictions on material that qualifies for the fissile material exemption.

Section 71.17 General license: NRC-approved package.

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

Section 71.19 Previously approved package.

Paragraphs (b) through (e) are redesignated as (a) through (d).

In redesignated (b)(2), the phrase “After December 31, 2003” is deleted. This will not change the requirement that packages used for a shipment to a location outside the United States will continue to be subject to multilateral approval as defined in the DOT’s regulations in 49 CFR 173.403 because all such shipments will occur after December 31, 2003.

Section 71.21 General license: Use of foreign approved package.

Paragraph (a) is revised to update the reference to 49 CFR 171.12 to 49 CFR 171.23.

Paragraph (d) is revised to clarify that the general licensee must comply with the requirements in § 71.21(d)(1) and (d)(2). Paragraph (d)(2) is revised by deleting its second 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

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

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 requirements and classification." This section also describes the availability of the documents.

Section 71.75 Qualification of special form radioactive material.

In paragraph (a)(5), the 1992 edition of ISO 9978 has been incorporated by reference for the alternate leak test methods for the qualification of special form material. The ISO/TR 4826 has been withdrawn by ISO and replaced by ISO 9978:1992(E). This change makes 10 CFR part 71 consistent with the DOT's requirements in 49 CFR 173, which incorporated ISO 9978:1992(E) in 2004.

In paragraph (b)(2)(ii), the description of the billet used in the percussion test has been changed to provide better clarity and to maintain consistency with the language used by the DOT in 49 CFR 173.469 by replacing "edges" with "edge." The edge corresponds to the circular edge at the face of the billet.

In paragraph (b)(2)(iii), the description of the sheet of lead used in the percussion test is changed to correct the thickness of the sheet of lead used in the percussion test to indicate that the thickness must not be more than 25 mm (1 inch) thick to be consistent with the thickness in TS-R-1.

In paragraph (d), subparagraphs (d)(1)(i) and (d)(1)(ii) have been added. Also, the 1999 edition of ISO 2919 has been incorporated by reference, replacing the reference to the 1980 edition of ISO 2919 for the alternate Class 4 impact test in paragraph (d)(1)(i) and the alternate Class 6 temperature test in paragraph (d)(2). The availability and other language incorporating this standard by reference is moved to new § 71.70. Paragraph (d)(1)(ii) allows the Class 5 impact tests prescribed in the 1999 edition of ISO 2919 to be used in place of the impact and percussion tests in paragraphs (b)(1) and (b)(2), if the specimen weighs less than 500 grams.

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 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 first sentence. This will remove the overlap between § 71.101(c)(1) and (c)(2) by making it clear

that licensees must notify the NRC before their first use of any package as required under § 71.101(c)(1), and certificate holders and applicants for a CoC will notify the NRC before the fabrication, testing, or modification of a package as required under § 71.101(c)(2).

Section 71.103 Quality assurance organization.

Footnote 2 is removed from paragraph (a). The activities described in the footnote are performed by certificate holders and applicants for a CoC. The footnote is unnecessary, because the requirements no longer rely on the use of the term “licensee” for those activities performed by certificate holders and applicants for a CoC.

Section 71.106 Changes to a quality assurance program.

This new section is added to establish requirements that will apply to changes to quality assurance programs. It allows some changes to a quality assurance program to be made without obtaining the prior approval of the NRC. Previously, all changes, no matter how insignificant, had to be approved by the NRC before they could be implemented. These provisions will allow changes to quality assurance programs that do not reduce commitments, such as those that involve administrative improvements and clarifications and editorial changes, to be made and implemented without NRC approval. Quality assurance program approval holders will still be required to get NRC approval before making changes to their quality assurance programs that would reduce their commitments to the NRC.

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 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

quantity of radioactive material that can be shipped in a package that contains both special form and normal form radioactive material. This equation increases the consistency between appendix A and TS-R-1.

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

Table A-1 is revised to change the A_1 value for Cf-252 from 5.0×10^{-2} TBq to 1.0×10^{-1} TBq, and from 1.4 Ci to 2.7 Ci. Footnote h is deleted, and the following corresponding changes are made: 1) the reference to footnote h is removed from Cf-252, 2) footnote i is redesignated as footnote h, and 3) the entry for molybdenum-99 (Mo-99) is revised to identify footnote h instead of footnote i. Footnote c in the entry for Ir-192 is moved, so that it is clear that it applies only to iridium in special form. Footnote c is revised to specifically state that the activity of iridium in special form may be determined through measurement at a prescribed distance from the source. Table A-1 is revised to include values for Kr-79. The A_1 and A_2 values for Kr-79 correspond to the A_1 and A_2 values in TS-R-1 and the specific activity is 4.2×10^4 TBq/g (1.1×10^6 Ci/g). The entry for Kr-81 is revised to reflect that it is no longer the first entry for the isotopes of krypton. In addition, footnote a is revised to identify the A_1 and/or A_2 values that include contributions from daughter radionuclides with half-lives of less than 10 days.

Table A-2 is revised to include values for Kr-79, reflect changes in TS-R-1 for the activity limit for exempt consignment for Te-121m and in the list of parent radionuclides and their progeny included in secular equilibrium in Table A-2 in footnote b. The value for the activity concentration for exempt material for Kr-79 is 1.0×10^3 Bq/g (2.7×10^{-8} Ci/g) and the value for the

activity limit for exempt consignment is 1.0×10^5 Bq (2.7×10^{-6} Ci). The activity limit for exempt consignment for Te-121m is revised from 1×10^5 Bq (2.7×10^{-6} Ci) to 1×10^6 Bq (2.7×10^{-5} Ci). In footnote b, the chains for the parent radionuclides Ce-134, Rn-220, Th-226, and U-240 are removed, and a chain for Ag-108m is added. This makes footnote b to Table A-2 consistent with footnote b to Table 2 in TS-R-1.

Table A-3 is revised to reflect changes in TS-R-1. In the second entry, the descriptive phrase “only alpha emitting radionuclides are known to be present” is changed to “alpha emitting nuclides, but no neutron emitters, are known to be present” to reduce the confusion caused by the current phrase because all alpha emitting radionuclides also emit other particles and/or gamma rays. In the third entry, the descriptive phrase “no relevant data are available” is changed to “neutron emitting nuclides are known to be present or no relevant data are available” to clarify that neutron-emitting radionuclides, or alpha emitters that also emit neutrons, such as Cf-252, Cf-254, and Cm-248, should be assigned to the third group. Footnote a indicates the appropriate value of A_1 for a group containing both alpha emitting radionuclides and beta or gamma emitting radionuclides when groups of radionuclides are based on the total alpha activity and the total beta and gamma activity.

VI. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act as well as

the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31883).

VII. Finding of No Significant Environmental Impact: Availability.

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this final rule. The Commission has concluded on the basis of an Environmental Assessment (ADAMS Accession No. ML14237A384) that this final rule is not a major Federal action significantly affecting the quality of the human environment.

Many of the changes fall under a categorical exclusion for which the Commission has previously determined that such actions, neither individually nor cumulatively, will have significant impacts on the human environment. The categorical exclusions in 10 CFR 51.22(c)(2) and 10 CFR 51.22(c)(3) were used in the Environmental Assessment. The categorical exclusion at 10 CFR 51.22(c)(2) applies to amendments to 10 CFR part 71 that are corrective or of a minor or non-policy nature and do not substantially modify the regulations.

The categorical exclusion at 10 CFR 51.22(c)(3) applies to amendments to 10 CFR part 71 that relate to—1) procedures for filing and reviewing applications for licenses or construction permits or early site permits or other forms of permission or for amendments to or renewals of licenses or construction permits or early site permits or other forms of permission; 2) recordkeeping requirements; 3) reporting requirements; 4) education, training, experience, qualification, or other employment suitability requirements; or 5) actions on petitions for rulemaking relating to these amendments.

Those changes not qualifying for a categorical exclusion were evaluated for their environmental impacts and include changes to 1) definitions, 2) the exemption of low-level materials, 3) the fissile material exemption for low-enriched fissile material, 4) alternate tests that may be used for the qualification of special form material, 5) preliminary determinations; 6) the A_1 and A_2 values for radionuclides, and 7) the exempt material activity concentrations and exempt consignment activity limits for radionuclides. The effects of these changes are addressed in more detail in the Environmental Assessment. The changes to the fissile material exemption will further reduce the potential for criticality during the transport of low-enriched fissile material under the fissile material exemption. Other changes, such as those relating to the exemption of low-level material, the A_1 and A_2 values for radionuclides, and the exempt material activity concentrations and exempt consignment activity limits for radionuclides have been found to have small or very small impacts. Some natural material and ore may be shipped without being regulated as hazardous material. The low-level material exemption is changed to allow some additional material to be transported without being regulated as hazardous material. The amount of transported material affected by this change is a very small fraction of the material that already qualifies for the exemption and will allow no greater activity than is already allowed for material that may already be transported under the exemption. Although there are changes to A_1 and A_2 values used to determine the type of packaging, the exempt material activity concentrations, and the exempt consignment activity limits for some radionuclides, the approach for determining the appropriate values has not changed, so there are very small impacts from these changes.

VIII. Paperwork Reduction Act Statement.

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0008. The burden to the public for these information collections is estimated to be a reduction of 1,700 hours (an average reduction of 55 hours per response), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0008), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

IX. Congressional Review Act.

This action is a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

X. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule affects NRC licensees who transport or deliver to a carrier for transport, relatively large quantities of radioactive material in a single package; holders of a 10 CFR part 71, Subpart H, quality assurance program description issued under 10 CFR parts 50, 71, or 72; and holders of a CoC for a transportation package. These entities do not typically fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC in 10 CFR 2.810.

XI. Regulatory Analysis.

The NRC has prepared a regulatory analysis (ADAMS Accession No. ML14237A383) of this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852; or at <http://www.regulations.gov> under Docket ID NRC-2008-0198.

XII. Backfitting and Issue Finality.

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) and the issue finality provisions in 10 CFR part 52 do not apply to this final rule, because this final rule does not establish any provisions that will impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required for this final rule, and the NRC did not prepare a backfit analysis for this final rule.

XIII. Criminal Penalties.

For the purpose of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the Commission is amending 10 CFR part 71 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule will be subject to criminal enforcement.

XIV. Compatibility of Agreement State Regulations.

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States’ and the NRC’s requirements. The NRC analyzed the rule in accordance with the procedure

established within part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (ADAMS Accession No. ML041770094). The compatibility categories assigned to the affected sections of 10 CFR part 71 are presented in the Compatibility Table in this section.

There are four compatibility categories (A, B, C, and D). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A is assigned to those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Compatibility Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B is assigned to those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Compatibility Category B program elements in an essentially identical manner. Compatibility Category C is assigned to those program elements that do not meet the criteria of Compatibility Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Compatibility Category C program elements. Compatibility Category D is assigned to those program elements that do not meet any of the criteria of Compatibility Category A, B, or C and, therefore, do not need to be adopted by Agreement States for purposes of compatibility. Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should

adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC is assigned to those program elements that address areas of regulation that cannot be relinquished to Agreement States under the AEA or the provisions of 10 CFR. These program elements are not adopted by the Agreement States.

The following table lists the parts and sections that are revised and their corresponding categorization under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs.” A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to adopt it again. The presence or absence of a bracket does not affect the compatibility category or the degree of uniformity required when an Agreement State adopts the requirement. The Agreement States have 3 years from the effective date of the final rule to adopt compatible regulations.

COMPATIBILITY TABLE

Section	Change	Subject	Compatibility	
			Existing	New ¹
71.0(d)(1)	Revised	Purpose and Scope	D	D
71.4	New	Definition Contamination	—	[B]
71.4	Revised	Definition Criticality Safety Index (CSI)	[B]	[B]
71.4	Revised	Definition Low Specific Activity (LSA) material	[B]	[B]
71.4	Revised	Definition Special form radioactive material	[B]	[B]

71.4	Revised	Definition Uranium – natural, depleted, enriched	[B]	[B]
71.6	Revised	Information Collection Requirements: OMB Approval	D	D
71.14(a)(1)	Revised	Exemption for low-level materials	[B]	[B]
71.14(a)(2)	Revised	Exemption for low-level materials	[B]	[B]
71.14(a)(3)	New	Exemption for low-level materials	—	[B]
71.15(d)	Revised	Exemption from classification as fissile material	[B]	[B]
71.17	Removal of brackets on Compatibility Category	General license: NRC-approved package	[B]	B
71.17(c)	Revised	General license: NRC-approved package	[B]	B
71.19	Revised	Previously approved package	NRC	NRC
71.21	Removal of brackets on Compatibility Category	General license: Use of foreign approved package	[B]	B
71.21(a)	Revised	General license: Use of foreign approved package	[B]	B
71.21(d)	Revised	General license: Use of foreign approved package	[B]	B
71.31(b)	Revised	Contents of application	NRC	NRC

71.38	Retitled and revised	Renewal of a certificate of compliance	NRC	NRC
71.70	New	Incorporations by reference	—	NRC
71.75	Revised	Qualification of special form radioactive material	NRC	NRC
71.85(a)	Revised	Preliminary determinations	[B]	NRC
71.85(b)	Revised	Preliminary determinations	[B]	NRC
71.85(c)	Revised	Preliminary determinations	[B]	NRC
71.85(d)	New	Preliminary determinations	—	B
71.91(a)	Revised	Records	D	C
71.91(b)	Revised Compatibility Category	Records	D	NRC
71.91(c)	Revised Compatibility Category	Records	D	C
71.91(d)	Revised Compatibility Category	Records	D	C
71.101(a)	Revised	Quality assurance requirements	D—For those States which have no users of Type B packages— other than industrial radiography**. C—Those States which have users of Type B packages— other than industrial radiography**. **Note: § 71.101(g) indicates that QA programs for industrial	C **Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).

			radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).	
71.101(b)	Revised Compatibility Category	Quality assurance requirements	<p>D—For those States which have no users of Type B packages—other than industrial radiography**.</p> <p>C—Those States which have users of Type B packages—other than industrial radiography**.</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections</p>	<p>C</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>

			referenced in this provision (§§ 71.101 through 71.137).	
71.101(c)(1)	Revised Compatibility Category	Quality assurance requirements	<p>D—For those States which have no users of Type B packages—other than industrial radiography**.</p> <p>C—Those States which have users of Type B packages—other than industrial radiography**.</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>C</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>
71.101(c)(2)	Revised	Quality assurance requirements	NRC	NRC
71.101(g)	Revised Compatibility Category Note	Quality assurance requirements	<p>C</p> <p>**Note: § 71.101(g) indicates that QA programs for</p>	<p>C</p> <p>**Note: § 71.101(g) indicates that QA programs for</p>

			<p>industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>
71.103(a)	Revised	Quality assurance organization	<p>D—For those States which have no users of Type B packages-other than industrial radiography**.</p> <p>[C]—Those States which have users of Type B packages-other than industrial radiography**.</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in</p>	<p>C</p> <p>**Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>

			this provision (§§ 71.101 through 71.137).	
71.103(b)	Revised Compatibility Category Note	Quality assurance organization	C—Those States which have users of Type B packages-other than industrial radiography**. **Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).	C **Note: § 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).
71.106	New	Changes to quality assurance program	—	C
71.135	Revised	Quality assurance records	D—For those States which have no users of Type B packages—other than industrial radiography**. C—For those States which have users of Type B packages—other than	C **Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will

			<p>industrial radiography**.</p> <p>**Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>
Appendix A	<p>Revise paragraphs IV.a. - IV.f.; redesignate paragraphs IV.c. - IV.f. as paragraphs IV.d. - IV.g.; add paragraph IV.c.; redesignate the text of paragraph V. as paragraph V.a.; and add paragraph V.b.</p>	<p>Determination of A₁ and A₂</p>	[B]	[B]
Appendix A, Table A-1	<p>Revise entries for Cf-252, Ir-192, Kr-81, and Mo-99; revise footnote a; delete footnote h; and</p>	<p>A₁ and A₂ Values for Radionuclides</p>	[B]	[B]

	redesignate footnote i as footnote h. Add entry for Kr-79.			
Appendix A, Table A-2	Add entry for Kr-79; revise entries for Kr-81 and Te-121m; and revise footnote b.	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides	[B]	[B]
Appendix A, Table A-3	Revise entries for column 1, "Contents," and add footnote a.	General Values for A ₁ and A ₂	[B]	[B]

¹ Where there is a change in the assigned compatibility category, a compatibility category is assigned. Where the content of the section has been significantly changed, a summary of the analysis is presented below. Changes in the assigned compatibility category have been made in §§ 71.4 (added for the definition of contamination), 71.70, 71.85, 71.91, 71.101, 71.103, 71.106, and 71.135.

In § 71.4, the definition of contamination will be designated Compatibility Category B, because it applies to activities that have direct and significant effects in multiple jurisdictions and it is also defined in the corresponding DOT regulations.

In §§ 71.17, 71.21, and 71.103 the compatibility category is unchanged, but the brackets were not retained because there are no corresponding DOT regulations.

The new § 71.70, "Incorporations by reference," will be designated Compatibility Category NRC, because the documents incorporated by reference are incorporated for use in § 71.75, which addresses activities under Federal jurisdiction.

Section 71.85, "Preliminary determinations," will be changed to make the requirements in § 71.85(a) through (c) apply to holders of a CoC. Paragraphs 71.85(a) through (c) are

designated as Compatibility Category NRC, because they apply exclusively to certificate holders and the granting of the package approval is reserved to the NRC. Paragraph 71.85(d) will be added and applies to licensees and it is designated as Compatibility Category B, because it applies to activities that have direct and significant effects in multiple jurisdictions and there is no corresponding DOT requirement.

The compatibility category for § 71.91, "Records," will be changed from Compatibility Category D to Compatibility Category C. In reaching an agreement with the NRC, the States have a general provision relating to records and for incident reporting. The recordkeeping requirements in § 71.91 include requirements associated with transportation, which may involve multiple jurisdictions. With the exception of § 71.91(b), the NRC is designating the compatibility of the requirements in § 71.91 as Compatibility Category C to require that the essential objectives of the requirements be adopted to avoid conflict, duplication, gaps, or other conditions that would jeopardize the orderly pattern in the regulation of agreement material on a nationwide basis, including creating an undue burden on interstate commerce through additional recordkeeping requirements; § 71.91(b) only applies to CoC holders and applicants and are designated as compatibility category NRC. The States are not required to adopt them in an essentially identical manner, as might be necessary if the requirements had a more direct and significant impact on multiple jurisdictions.

In § 71.101, the compatibility category will be simplified with the removal of the separate compatibility category for States that do not have a user of a Type B package. If a State does not have a user of a Type B package, the State is able to seek an exemption from the requirement to make their requirement compatible. The State requirements only need to be essentially compatible with respect to the requirements as they apply to licensees, because the application of the requirements to CoC holders and applicants would be performed by the NRC.

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

In § 71.103, the compatibility category for some users of packages was not designated. The compatibility category will be simplified by removing the separate compatibility category for States that do not have a user of a Type B package and by removing the bracket around the compatibility category for § 71.103(a). If a State does not have a user of a Type B package, the State can seek an exemption from the requirement to make their requirement compatible. The State requirements only need to be essentially compatible with respect to the requirements as they apply to licensees, because the application of the requirements to CoC holders and applicants will be performed by the NRC. The note that references the quality assurance programs for industrial radiographers will be updated by changing § 71.12(b) to § 71.17(b).

The new § 71.106, "Changes to quality assurance program," will apply to licensees and holders of, or applicants for, a CoC. The assigned compatibility category is consistent with the other quality assurance requirements that apply to licensees. The State requirements only need to be essentially compatible with respect to the requirements as they apply to licensees, because the application of the requirements to CoC holders and applicants will be performed by the NRC.

In § 71.135, the compatibility category will be simplified by removing the separate compatibility category for States that do not have a user of a Type B package. If a State does not have a user of a Type B package, the State can seek an exemption from the requirement to make their requirement compatible. The State requirements only need to be essentially compatible with respect to the requirements as they apply to licensees, because the application of the requirements to CoC holders and applicants will be performed by the NRC. The note that

references the quality assurance programs for industrial radiographers is updated by changing § 71.12(b) to § 1.17(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.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

1. The authority citation for part 71 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 2297f); Energy Reorganization Act secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act sec. 180 (42 U.S.C. 10175); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

Section 71.97 also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789-790.

§ 71.0 [Amended]

2. In § 71.0, paragraph (d)(1), remove the reference “§§ 71.20 through 72.23” and add, in its place, the reference “§§ 71.21 through 71.23.”

3. In § 71.4, add in alphabetical order the definition of “*contamination*,” and revise the definitions of “*Criticality Safety Index (CSI)*,” “*Low Specific Activity (LSA) material*,” “*Special form radioactive material*,” and “*Uranium—natural, depleted, enriched*” to read as follows:

§ 71.4 Definitions.

* * * * *

Contamination means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm² (1×10^{-5} µCi/cm²) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² (1×10^{-6} µCi/cm²) for all other alpha emitters.

(1) *Fixed contamination* means contamination that cannot be removed from a surface during normal conditions of transport.

(2) *Non-fixed contamination* means contamination that can be removed from a surface during normal conditions of transport.

* * * * *

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

* * * * *

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

(1) LSA-I.

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

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

(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) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and

(3) It satisfies the requirements of § 71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before **[INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]** in accordance with the requirements of § 71.75(d) of this section in effect before **[INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]** may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

* * * * *

Uranium – natural, depleted, enriched:

(1) Natural uranium means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

4. In § 71.6, revise paragraph (b) to read as follows:

§ 71.6 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 71.5, 71.7, 71.9, 71.12, 71.17, 71.19, 71.22, 71.23, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.47, 71.85, 71.87, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.106, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, and appendix A, paragraph II.

5. In § 71.14, revise paragraphs (a)(1) and (2), and add paragraph (a)(3) to read as follows:

§ 71.14 Exemption for low-level materials.

(a) * * *

(1) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, 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, 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.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in appendix A, Table A-2, or Table A-3 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in appendix A, Table A-2, or Table A-3 of this part.

(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in § 71.4.

* * * * *

6. In § 71.15, revise paragraph (d) to read as follows:

§ 71.15 Exemption from classification as fissile material.

* * * * *

(d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

* * * * *

7. In § 71.17, revise paragraph (c) to read as follows:

§ 71.17 General license: NRC-approved package.

* * * * *

(c) Each licensee issued a general license under paragraph (a) of this section shall—

(1) Maintain a copy of the Certificate of Compliance, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and

(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

* * * * *

8. In § 71.19, redesignate paragraphs (b) through (e) as paragraphs (a) through (d), and revise newly redesignated paragraph (b)(2) to read as follows:

§ 71.19 Previously approved package.

* * * * *

(b) * * *

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in the DOT's regulations at 49 CFR 173.403.

* * * * *

9. In § 71.21, revise paragraphs (a) and (d) to read as follows:

§ 71.21 General license: Use of foreign approved package.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

* * * * *

(d) Each licensee issued a general license under paragraph (a) of this section shall—

(1) Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of this part.

§ 71.31 [Amended]

10. In § 71.31, paragraph (b), remove the reference “§ 71.13” and add, in its place, the reference “§ 71.19.”

11. Revise § 71.38 to read as follows:

§ 71.38 Renewal of a certificate of compliance.

(a) Except as provided in paragraph (b) of this section, each Certificate of Compliance expires at the end of the day, in the month and year stated in the approval.

(b) In any case in which a person, not less than 30 days before the expiration of an existing Certificate of Compliance issued pursuant to the part, has filed an application in proper form for renewal, the existing Certificate of Compliance for which the renewal application was filed shall not be deemed to have expired until final action on the application for renewal has been taken by the Commission.

(c) In applying for renewal of an existing Certificate of Compliance, an applicant may be required to submit a consolidated application that is comprised of as few documents as

possible. The consolidated application should incorporate all changes to its certificate, including changes that are incorporated by reference in the existing certificate.

12. Add § 71.70 to subpart F to read as follows:

§ 71.70 Incorporations by reference.

(a) The materials listed in this section are incorporated by reference in the corresponding sections noted and made a part of the regulations in part 71. These incorporations by reference were approved by the Director of the *Federal Register* under 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval. A notice of any changes made to the material incorporated by reference will be published in the *Federal Register* and the material must be available to the public. The materials are available for purchase at the corresponding address noted in paragraph (b) of this section. The materials can also be examined at the NRC's Public Document Room, O1-F21, 11555 Rockville Pike, Rockville, Maryland 20852 or at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-5610; e-mail: Library.Resource@nrc.gov. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 1-202-741-6030 or go to <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(b) The following material is available for purchase from the American National Standards Institute, 25 West 43rd Street, 4th floor, New York, NY 10036, 212-642-4900, <http://www.ansi.org>, or info@ansi.org.

(1) ISO 9978:1992(E), "Radiation protection — Sealed radioactive sources — Leakage test methods," First Edition (February 15, 1992), incorporation by reference approved for § 71.75(a).

(2) ISO 2919:1999(E), "Radiation protection — Sealed radioactive sources — General requirements and classification," Second Edition (February 15, 1999), incorporation by reference approved for § 71.75(d).

13. In § 71.75, revise paragraphs (a)(5), (b)(2)(ii), (b)(2)(iii), (d)(1), and (d)(2) to read as follows:

§ 71.75 Qualification of special form radioactive material.

(a) * * *

(5) A specimen that comprises or simulates radioactive material contained in a sealed capsule need not be subjected to the leaktightness procedure specified in this section, provided it is alternatively subjected to any of the tests prescribed in ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods" (incorporated by reference, see § 71.70).

(b) * * *

(2) * * *

(ii) The flat face of the billet must be 25 millimeters (mm) (1 inch) in diameter with the edge rounded off to a radius of 3 mm ± 0.3 mm (0.12 in ± 0.012 in);

(iii) The lead must be hardness number 3.5 to 4.5 on the Vickers scale and not more than 25 mm (1 inch) thick, and must cover an area greater than that covered by the specimen;

* * * * *

(d) * * *

(1) The impact test and the percussion test of this section, provided that the specimen is:

(i) Less than 200 grams and alternatively subjected to the Class 4 impact test prescribed in ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70); or

(ii) Less than 500 grams and alternatively subjected to the Class 5 impact test prescribed in ISO 2919:1999(E), "Radioactive protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70); and

(2) The heat test of this section, provided the specimen is alternatively subjected to the Class 6 temperature test specified in ISO 2919:1999(E), "Radioactive protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70).

14. In § 71.85, revise paragraphs (a), (b), and (c) and add paragraph (d) to read as follows:

§ 71.85 Preliminary determinations.

* * * * *

(a) The certificate holder shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the certificate holder shall test the containment system at an internal pressure at least

50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure;

(c) The certificate holder shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC. Before applying the model number, the certificate holder shall determine that the packaging has been fabricated in accordance with the design approved by the Commission; and

(d) The licensee shall ascertain that the determinations in paragraphs (a) through (c) of this section have been made.

§ 71.91 [Amended]

15. In § 71.91, introductory text of paragraph (a), remove the reference “§ 71.10” and add, in its place, the reference “§ 71.14.”

16. In § 71.101, revise paragraphs (a) and (c)(2) to read as follows:

§ 71.101 Quality assurance requirements.

(a) *Purpose.* This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that

apply to design, fabrication, testing, and modification of packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

* * * * *

(c) * * *

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

* * * * *

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

§ 71.103 Quality assurance organization.

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

* * * * *

18. Add § 71.106 to subpart H to read as follows:

§ 71.106 Changes to quality assurance program.

(a) Each quality assurance program approval holder shall submit, in accordance with § 71.1(a), a description of a proposed change to its NRC-approved quality assurance program that will reduce commitments in the program description as approved by the NRC. The quality assurance program approval holder shall not implement the change before receiving NRC approval.

(1) The description of a proposed change to the NRC-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of this part.

(2) [Reserved]

(b) Each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with § 71.1(a). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

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

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

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

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

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

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

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 must include changes to the quality assurance program as required by § 71.106, the

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

20. In appendix A to part 71:

a. Revise paragraphs IV.a. and IV.b., redesignate paragraphs IV.c. through IV.f. as paragraphs IV.d. through IV.g., add new paragraph IV.c., revise newly redesignated paragraphs IV.d. through IV.g., redesignate paragraph V. as paragraph V.a., and add new paragraph V.b.;

b. In Table A-1, add an entry for Kr-79 in alphanumeric order; revise the entries for Cf-252, Ir-192, Kr-81, and Mo-99; revise footnotes a and c; remove footnote h; and redesignate footnote i as footnote h;

c. In Table A-2, add the entry for Kr-79 in alphanumeric order, revise the entries for Kr-81 and Te-121m, and revise footnote b; and

d. In Table A-3, revise the second and third entries and add a new footnote a.

The additions and revisions read as follows:

Appendix A to Part 71 – Determination of A₁ and A₂

* * * * *

IV. * * *

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

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

where B(i) is the activity of radionuclide i in special form, and A₁(i) is the A₁ 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 A₂(i) is the A₂ value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that 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, A₁(i) is the A₁ value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A₂(j) is the A₂ value for radionuclide j.

d. Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where $f(i)$ is the fraction of activity for radionuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for radionuclide i .

e. Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where $f(i)$ is the fraction of activity for radionuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for radionuclide i .

f. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where $f(i)$ is the fraction of activity concentration of radionuclide i in the mixture and $[A](i)$ is the activity concentration for exempt material containing radionuclide i .

g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A(i) is the activity limit for exempt consignments for radionuclide i.

V. * * *

b. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV of this appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

* * * * *

Table A-1—A₁ and A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
*	*	*		*	*	*	*
Cf-252		1.0x10 ⁻¹	2.7	3.0x10 ⁻³	8.1x10 ⁻²	2.0x10 ¹	5.4x10 ²
*	*	*		*	*	*	*
Ir-192		1.0 ^c	2.7x10 ^{1c}	6.0x10 ⁻¹	1.6x10 ¹	3.4x10 ²	9.2x10 ³
*	*	*		*	*	*	*
Kr-79	Krypton (36)	4.0	1.1x10 ²	2.0	5.4x10 ¹	4.2x10 ⁴	1.1x10 ⁶
Kr-81		4.0x10 ¹	1.1x10 ³	4.0x10 ¹	1.1x10 ³	7.8x10 ⁻⁴	2.1x10 ⁻²
*	*	*		*	*	*	*
Mo-99 (a)(h)		1.0	2.7x10 ¹	6.0x10 ⁻¹	1.6x10 ¹	1.8x10 ⁴	4.8x10 ⁵
*	*	*		*	*	*	*

^a A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:

Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I-135	Xe-135m

Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214
U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243
Bk-249	Am-245
Cf-253	Cm-249

* * * * *

^c The activity of 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 from the source.

* * * * *

^h A₂ = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

* * * * *

**Table A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT
CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES**

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
*	*	*	**	*	*
Kr-79	Krypton (36)	1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Kr-81		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
*	*	*	**	*	*
Te-121m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
*	*	*	**	*	*

* * * * *

^b Parent nuclides and their progeny included in secular equilibrium are listed as follows:

- Sr-90 Y-90
- Zr-93 Nb-93m
- Zr-97 Nb-97
- Ru-106 Rh-106
- Ag-108m Ag-108
- Cs-137 Ba-137m
- Ce-144 Pr-144
- Ba-140 La-140
- Bi-212 Tl-208 (0.36), Po-212 (0.64)
- Pb-210 Bi-210, Po-210
- Pb-212 Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Rn-222 Po-218, Pb-214, Bi-214, Po-214
- Ra-223 Rn-219, Po-215, Pb-211, Bi-211, Tl-207
- Ra-224 Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Ra-226 Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
- Ra-228 Ac-228
- Th-228 Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212(0.64)
- Th-229 Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
- Th-nat Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Th-234 Pa-234m
- U-230 Th-226, Ra-222, Rn-218, Po-214
- U-232 Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- U-235 Th-231
- U-238 Th-234, Pa-234m
- U-nat Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
- Np-237 Pa-233
- Am-242m Am-242
- Am-243 Np-239

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TABLE A-3—GENERAL VALUES FOR A₁ and A₂

Contents	A ₁		A ₂		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Ba)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
*		*	*	*	*	*		*
Alpha emitting nuclides, but no neutron emitters, are known to be present (a)	2x10 ⁻¹	5.4x10 ⁰	9x10 ⁻⁵	2.4x10 ⁻³	1x10 ⁻¹	2.7x10 ⁻¹²	1x10 ³	2.7x10 ⁻⁸
Neutron emitting nuclides are known to be present or no relevant data are available	1x10 ⁻³	2.7x10 ⁻²	9x10 ⁻⁵	2.4x10 ⁻³	1x10 ⁻¹	2.7x10 ⁻¹²	1x10 ³	2.7x10 ⁻⁸

^a If beta or gamma emitting nuclides are known to be present, the A₁ value of 0.1 TBq (2.7 Ci) should be used.

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Dated at Rockville, Maryland, this _____ day of _____, 2014.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.