RULEMAKING ISSUE
(Affirmation)

September 24, 2014 SECY-14-0100

FOR: The Commissioners

FROM: Mark Satorius
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

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

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BACKGROUND:

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

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

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

DISCUSSION:

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

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

- The final rule is changing the exemption for natural materials and ores containing naturally occurring radionuclides to be consistent with the international transport regulations by allowing natural materials and ores that have been processed to qualify for the exemption.

- The concept of processing ores for purposes other than radioactive material content is added to the provisions that apply to natural materials and ores in the exemptions for low-level materials in § 71.14, "Exemption for low-level materials."

- A definition of "contamination" corresponding to the definition in TS-R-1 is added to § 71.4, "Definitions." The following definitions in 10 CFR 71.4 are amended to reflect the

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

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

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

- The NRC is changing some values in Tables A-1, "A1 and A2 Values for Radionuclides," A-2, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides," and A-3, "General Values for A_1 and A_2," of Part 71 Appendix A to align with IAEA's TS-R-1 values.

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

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

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

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

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

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

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

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

Public Comment Analysis

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

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

Guidance

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

AGREEMENT STATE COMPATIBILITY:

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

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

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

Public Meeting on Implementation of the NRC's Final Rule

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

COMMITMENTS:

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

RECOMMENDATIONS:

That the Commission:

1. Approve publication of the final rule in the *Federal Register* (Enclosure 1).

2. Certify that this final rule, if adopted, will not have significant impact on a substantial number of small entities, to satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b). This certification is included in the enclosed *Federal Register* notice.

3. Note:

    a. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

    b. A final Regulatory Analysis has been prepared for this final rule (Enclosure 2).

    c. A final Environmental Assessment has been prepared for this final rule (Enclosure 3).

    d. The NRC staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 (5 U.S.C 804(2)) and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed.

    e. The appropriate Congressional committees will be informed.

    f. A press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the Federal Register.

    g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to OMB for its review and approval before publication of the final rule in the *Federal Register*.

RESOURCES:

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

COORDINATION:

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

/RA Michael F. Weber/

Mark Satorius
Executive Director
for Operations

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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-AI11

[NRC-2008-0198]

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is amending its regulations for the packaging and transportation of radioactive material. These amendments make conforming changes to the NRC's regulations based on the 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.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-3781; e-mail: Solomon.Sahle@nrc.gov.

SUPPLEMENTARY INFORMATION:

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 expericence.

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/cm^2 (1x10^{-5} µCi/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1x10^{-6} µCi/cm^2) for all other alpha emitters. The derived values used in the definition are conservative with respect to transportation. Quantities of radioactive substances below these values will result in small amounts of exposure during normal conditions of transportation and will contribute insignificant exposures under accident conditions.

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

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

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

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 4826[3]. 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 A_1 and A_2 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, "A_1 and A_2 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 A_1 and A_2 values for Cf-252; 3) revises footnote a to include the list of parent radionuclides whose A_1 and A_2 values include contributions from daughter radionuclides with half-lives of less than 10 days; 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 A_1 and A_2 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 A_1 value for Cf-252 to the value that previously applied to domestic transportation. The NRC is adopting the A_1 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 A_1 and A_2," 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 $1x10^5$ Bq ($2.7x10^{-6}$ Ci) to $1x10^6$ Bq ($2.7x10^{-5}$ 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 $9x10^{-5}$ TBq ($2.4x10^{-3}$ 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 Assurande (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 homogenous mixture of uranium enriched to a maximum of 1 percent) are not capable of obtaining criticality, irrespective of the mass or size of the system. The fissile material exemption in § 71.15(d) also limits the quantity of some less common moderating materials (beryllium, graphite, and hydrogenous material enriched in deuterium), because the presence of these materials has the potential to reduce the minimum critical enrichment, thereby increasing the potential for criticality with uranium of lower enrichment. Therefore, homogeneous materials containing uranium enriched to no more than 1 percent by weight and subject to the noted restrictions on moderators are inherently safe from a potential criticality and do not need to be limited by mass or size to be subcritical during transport. However, uranium enriched to less than 5 percent by weight is most reactive when it is in a heterogeneous configuration; therefore, the minimum 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 [($5x10^{-3}$ 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 homogenously 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. <u>Such objects in the transportation process, or in storage pending future transportation, need not be licensed under this chapter</u>."

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 $5.0x10^{-2}$ TBq to $1.0x10^{-1}$ 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 $4.2x10^{4}$ TBq/g ($1.1x10^{6}$ 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 $1.0x0^{3}$ Bq/g ($2.7x10^{-8}$ Ci/g) and the value for the

activity limit for exempt consignment is $1.0x10^5$ Bq ($2.7x10^{-6}$ Ci). The activity limit for exempt consignment for Te-121m is revised from $1x10^5$ Bq ($2.7x10^{-6}$ Ci) to $1x10^6$ Bq ($2.7x10^{-5}$ 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	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 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	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).

			referenced in this provision (§§ 71.101 through 71.137).	
71.101(c)(1)	Revised Compatibility Category	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 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).
71.101(c)(2)	Revised	Quality assurance requirements	NRC	NRC
71.101(g)	Revised Compatibility Category Note	Quality assurance requirements	C ****Note:** § 71.101(g) indicates that QA programs for	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 § 71.12(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).	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).
71.103(a)	Revised	Quality assurance organization	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 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	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).

			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

			industrial radiography**. **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).	satisfy those sections referenced in this provision (§§ 71.101 through 71.137).
Appendix A	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.	Determination of A_1 and A_2	[B]	[B]
Appendix A, Table A-1	Revise entries for Cf-252, Ir-192, Kr-81, and Mo-99; revise footnote a; delete footnote h; and	A_1 and A_2 Values for Radionuclides	[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 ($1x10^{-5}$ μCi/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm2 ($1x10^{-6}$ μCi/cm^2) 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 2×10^{-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/in^2) 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 A_1 and A_2

* * * * *

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 $A_1(i)$ is the A_1 value for radionuclide i.

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

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

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

c. If the package contains both special and normal form radioactive material, the activity 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, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

d. Alternatively, the 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—A_1 and A_2 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]	$2.7x10^{1}$[c]	$6.0x10^{-1}$	$1.6x10^{1}$	$3.4x10^{2}$	$9.2x10^{3}$
*	*	*		*	*	*	*
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] A_1 and/or A_2 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] A_2 = 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)	$1.0x10^{3}$	$2.7x10^{-8}$	$1.0x10^{5}$	$2.7x10^{-6}$
Kr-81		$1.0x10^{4}$	$2.7x10^{-7}$	$1.0x10^{7}$	$2.7x10^{-4}$
*	*	*	**	*	*
Te-121m		$1.0x10^{2}$	$2.7x10^{-9}$	$1.0x10^{6}$	$2.7x10^{-5}$
*	*	*	**	*	*

* * * * *

[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

* * * * *

TABLE A-3—GENERAL VALUES FOR A_1 and A_2

Contents	A_1		A_2		Activity concen-tration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consign-ments (Ba)	Activity limits for exempt consign-ments (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 A_1 value of 0.1 TBq (2.7 Ci) should be used.

* * * * *

Dated at Rockville, Maryland, this_____ day of_____, 2014.

For the Nuclear Regulatory Commission.

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

Regulatory Analysis for Final Rulemaking - Compatibility with IAEA Transportation Standards (10 CFR Part 71)

September 2014

Table of Contents

EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) regulates the safe transportation of byproduct material under Part 71 of Title 10 of the Code of Federal Regulations (10 CFR), "Packaging and Transportation of Radioactive Material." In consultation with the U.S. Department of Transportation (DOT), the NRC is amending its regulations for the packaging and transportation of radioactive material. These amendments will make conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) regulations for the international transportation of radioactive material and to maintain consistency with DOT regulations. The final NRC rule, in combination with a final DOT rule amending Title 49 of the Code of Federal Regulations (49 CFR) (79 FR 40590; July 11, 2014), will bring United States regulations into general accord with the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1).

In addition, the NRC is making other revisions to 10 CFR Part 71. These other revisions include NRC-initiated changes that will: 1) update administrative procedures for the quality assurance (QA) 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 determinations; and 5) make other editorial changes.

This Regulatory Analysis (RA) provides an evaluation of three alternatives. The preferred alternative is Alternative 3 (see Section 2.3 of this document), which will change regulations as specified in the rule.

The RA makes the following key findings:

- Total cost to Industry: The rule will result in a one-time cost to the industry of approximately $95,000 (approximately $400 per licensee). The rule will have a total annual savings to the industry of approximately $112,000 (approximately $450 per licensee).

- Total cost to the NRC: The rule will result in a one-time cost to the NRC of approximately $5,000, followed by annual cost savings of approximately $22,000.

- Total cost to Agreement States: Agreement States will be required to amend their regulations consistent with the final rule. The rule will result in a one-time cost to Agreement States of approximately $1.8 million.

- Decision Rationale: The final rule will make the NRC's Part 71 requirements compatible with IAEA and DOT regulations. The NRC-initiated regulatory changes will improve regulatory efficiency, thereby providing benefits to licensees and to the Agreement States. The final rule is expected to slightly reduce impacts to public health and safety.

The final rule is planned for publication in the *Federal Register* in 2015.

ACRONYMS

ADAMS	Agencywide Documents Access and Management System
AS	Agreement States
CFR	*Code of Federal Regulations*
CRCPD	Conference of Radiation Control Program Directors
CoC	Certificate of Compliance
CSI	Criticality Safety Index
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
FTE	Full Time Equivalent
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
LSA	Low Specific Activity
NRC	U.S. Nuclear Regulatory Commission
NPV	Net Present Value
NUREG	Nuclear Regulatory Publication
OMB	Office of Management and Budget
QA	Quality Assurance
RA	Regulatory Analysis
SSR-6	IAEA Specific Safety Requirements Number SSR-6, “Regulations for the Safe Transport of Radioactive Material”
TS-R-1	IAEA Safety Requirements Number TS-R-1: “Regulations for the Safe Transport of Radioactive Material” 2009 edition

1. STATEMENT OF THE PROBLEM AND OBJECTIVE OF THE RULEMAKING

The NRC is amending its 10 CFR Part 71 regulations for packaging and transportation of radioactive material. These amendments will make NRC regulations consistent with 2009 revisions to the IAEA's transportation standards in TS-R-1. The TS-R-1 represents an accepted set of requirements that provides a high level of safety in the packaging and transportation of radioactive materials and provides 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 can reduce risks associated with the import and export of radioactive material.

The IAEA revises its transportation standards periodically to reflect acquired knowledge and experience. The NRC periodically updates its transportation regulations in10 CFR Part 71 to reflect the changes in the IAEA's transportation standards and to maintain compatibility with the DOT regulations.

The NRC co-regulates domestic transportation of radioactive material with the DOT. The DOT regulations regarding transportation of radioactive materials are in Title 49 Parts 107, and 171-180. The NRC and the DOT are publishing final rules with the dual purpose to achieve compatibility with IAEA's transportation standards and to improve regulatory efficiency by maintaining a consistent regulatory framework. To achieve compatibility with TS-R-1, the DOT published amendments to its regulations in a final rule dated July 11, 2014 (76 FR 40590). The NRC is also making other changes that do not affect compatibility with the IAEA TS-R-1 or the DOT hazardous material regulations, as discussed in more detail later in this document.

In November 2012, the IAEA issued new standards for the safe transport of radioactive material and designated them as "Specific Safety Requirements Number SSR-6" (SSR-6). This NRC rulemaking does not incorporate the 2012 IAEA SSR-6 changes. The NRC will review the SSR-6 changes to determine if additional future conforming changes to 10 CFR Part 71 are warranted.

In addition to making changes for compatibility with IAEA and DOT, the NRC is also 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 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 determinations; and 5) make editorial revisions to correct and clarify certain other requirements.

Hazardous materials, including radioactive material, are transported regularly as part of international commerce. Shipping companies that are active in the international transport of radioactive material must comply with international legal requirements that are often based on standards published by the IAEA and adopted by IAEA Member States. The U.S. adopts many of the IAEA international transportation regulations into its domestic transport regulations, with regulatory changes implemented through the rulemaking process. The NRC and the DOT strive to maintain consistency or compatibility between the domestic transport regulations and the IAEA's transportation standards. The effort to maintain consistency or compatibility between national regulations and internationally accepted requirements is known as "harmonization."

Harmonization represents the effort to increase the consistency or compatibility between national regulations and the internationally accepted requirements, within the constraints of an existing national legal and regulatory framework. The NRC and the DOT harmonized domestic transport regulations with changes made to TS-R-1 over the past several years. These changes will be implemented with a slight cost to the public and domestic regulatory authorities responsible for implementing the proposed changes.

The NRC and the DOT adopted a memorandum of understanding (44 FR 38690; July 2, 1979) to delineate their respective roles in the regulation of the transportation of radioactive material. The NRC, in consultation with the DOT, develops safety standards for the design and performance of packages for fissile materials and for quantities of other radioactive materials, other than LSA materials, exceeding Type A limits. The areas where the NRC develops safety standards include: criticality control and quality assurance of packaging design, fabrication, testing, maintenance, and use.

This analysis presents background material, rulemaking objectives, alternatives considered, input assumptions, analysis of the costs and benefits of the proposed rule, and decision rationale. It describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

2. IDENTIFICATION OF ALTERNATIVE APPROACHES

The following sections describe the regulatory options that the NRC considered in order to meet the rulemaking objectives identified in the previous section. The NRC considered three alternatives for the rule, described in the following sections. The full lists of changes that indicate their relationship to the alternatives are provided in Table 4-3, which summarizes the costs by entity over a 10-year analysis period.

2.1 Alternative 1: The No-Action Alternative

Alternative 1 is the No-Action alternative and would maintain the status quo. Under Alternative 1, the NRC would make no changes to the current regulations in 10 CFR Part 71, and there would be no costs or benefits. Alternative 1 would avoid costs that the rule would impose; however, it would allow greater divergence between the international standards and the domestic regulations. Because radioactive material is routinely imported and exported, consistency between domestic and international transportation regulations benefits international commerce. Differences in domestic and international regulations can make it more complicated and expensive to import or export radioactive material and inhibit trade. Under this alternative, there would be no changes to enhance the current level of protection for public health and safety. Also, there would be no changes made to improve regulatory efficiency and the resulting benefits to certain segments of the transport industry. This is the baseline of the RA.

2.2 Alternative 2: IAEA-DOT Compatibility

This alternative would amend the NRC regulations to increase consistency and compatibility with TS-R-1 and with changes implemented by the DOT and does not include any additional NRC-initiated changes. These amendments include:

- Section 71.4, Definitions. A definition of contamination is added, and the existing definitions of “Criticality Safety Index (CSI),” “Low Specific Activity (LSA) material,” “special form radioactive material,” and “Uranium ─ natural, depleted, enriched” are revised.

- Section 71.14, Exemption for low-level material. Paragraph (a) is revised to allow natural material and ores that contain naturally occurring radionuclides to qualify for the exemption, if such material has “been processed for purposes other than the extraction of the radionuclides.” Section 71.14(a)(3) is added to provide an exemption for non-radioactive solid objects which have radioactive substances present on their surfaces, provided that the quantity of radioactive substances is below that which is stated in the new contamination definition.

- Section 71.75, Qualification of special form radioactive material. Paragraph (d) is amended to update the International Organization for Standardization (ISO) Class 4 impact test and ISO Class 6 temperature test to those prescribed in ISO 2919:1999(E), “Radiation protection — Sealed radioactive sources — General requirements and classification,” and will allow the ISO Class 5 impact tests prescribed in ISO 2919:1999(E) to be used if the specimen weighs less than 500 grams.

- Appendix A, Table A-1, “A_1 and A_2 Values for Radionuclides.” The table is amended to add an entry for krypton-79 (Kr-79); revise listed values for californium-252 (Cf-252), and revise footnotes to be consistent with TS-R-1.

- Appendix A, Table A-2, “Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides.” The table is amended to add an entry for Kr-79, revise listed values for tellurium-121m (Te-121m), and revise footnote b.

2.3 Alternative 3: IAEA-DOT Compatibility and NRC-Initiated Changes

This alternative includes all of the changes comprising Alternative 2 and additional NRC-initiated changes.

These NRC-initiated changes include:

- Section 71.15, Exemption from classification as fissile material. The exemption in paragraph (d) that applies to 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, (hereafter referred to as uranium enriched to a maximum of 1 percent) is revised to additionally require that such material be distributed homogeneously and not form a lattice arrangement, in order to qualify for this exemption.

- Section 71.38, Renewal of a certificate of compliance. This section is retitled and revised to remove references to renewals of QA program approvals, which will no longer be required.

- Section 71.85, “Preliminary determinations.” This section is revised to replace “licensee” with “certificate holder” in paragraphs (a), (b), and (c); and paragraph (d) is added to require that licensees ascertain that the preliminary determinations made by the certificate holder (paragraphs (a) – (c)) have been made.

- Section 71.106, “Changes to quality assurance program.” This section is added to revise the process for holders of a QA program approval to make changes to an approved QA program and requires periodic reporting of those changes that do not require prior NRC approval.

- Section 71.135, “Quality assurance records.” This section is revised to include changes made to an approved quality assurance program as a quality assurance record.

The NRC has estimated the benefits and costs of these alternatives. They are evaluated and described in Sections 3 and 4 of this RA. The rationale for the NRC decision to pursue Alternative 3 is discussed in Section 5.

3. ESTIMATION AND EVALUATION OF BENEFITS AND COSTS

This section examines the benefits and costs expected to result from the changes to 10 CFR Part 71. The benefits and costs are analyzed for Alternatives 2 and 3 and are set forth by the societal attributes that are considered important for the evaluation of the amendments.

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rule is expected to affect, using the list of potential attributes in Chapter 5 of NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” issued January 1997, and in Chapter 4 of NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Revision 4, issued September 2004. This evaluation considered each attribute listed in Chapter 5 of NUREG/BR-0184[1]. The basis for selecting those attributes is presented later in this document.

Affected attributes include the following:

- **Industry Operation**: The NRC is making changes that will make the regulation of QA programs more efficient. The NRC will issue QA program approvals that will not expire, so that QA program renewal applications will no longer be required. The NRC is also allowing those changes that do not reduce the commitments in an approved QA program to be made without prior NRC approval. Additional natural material and ores that contain naturally occurring radionuclides might qualify for the exemption of low-level radioactive material, which will facilitate the transportation of these materials and reduce shipping costs. In aggregate, the NRC expects that the efficiencies gained from these regulatory changes will result in cost savings to the industry. Radioactive material is imported and exported and consistency between domestic and international transportation regulations reduces cost to the industry. This rule will allow industry to continue to benefit from harmonized regulations.

[1] (http://pbadupws.nrc.gov/docs/ML0501/ML050190193.pdf)

- **Industry Implementation**: When the final rule is adopted/promulgated, affected licensees will need to purchase a copy of the ISO standards as well as maintain awareness of changes to the relevant transportation regulations. Each licensee will need to read the new regulations and determine actions necessary for compliance. Changes to 10 CFR 71.75(d), which will incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams, will require affected licensees to incur a one-time cost for the purchase of equipment.

- **NRC Implementation**: With the publication of the final rule, the NRC will re-issue QA program approvals with no expiration date. The NRC will also review and evaluate State regulations developed by the Conference of Radiation Control Program Directors (CRCPD) and will review amendments to Agreement State regulations for compatibility.

- **Other Governments**: Agreement States will incur costs associated with efforts to amend their regulations and guidance, which may also include costs associated with the CRCPD development of Suggested State Regulations for Control of Radiation. Agreement States will incur one-time costs to amend regulations to implement Alternative 2 or Alternative 3.

  The U.S. Department of Energy (DOE) certifies its packages, and it may use them for the transportation of Class 7 (radioactive) material when evaluated, approved and certified using standards equivalent to those specified in 10 CFR Part 71. The DOT also requires that for Class 7 material shipped by the DOE, that the packages be marked and prepared for shipment in a manner equivalent to that required of NRC licensees. Consequently, the DOE will need to comply with amendments to the fissile material exemption.

- **Regulatory Efficiency**: The amendments include changes to harmonize 10 CFR Part 71 with the international standards and to maintain consistency with the DOT regulations. This will help to achieve and maintain regulatory efficiency. The rule will incorporate by reference consensus standards used for the qualification of special form material, which also contributes to regulatory efficiency. Changes to the general license provisions will provide additional clarity as to the responsibilities of the general licensee, which will improve compliance and regulatory oversight. Changes to the requirements for making preliminary determinations will make the requirements more consistent with current practice and improve compliance. In Appendix A, improving the row headings in Table A-3 for clarity, and correcting and adding equations for calculating values for mixtures of radionuclides will also contribute to improved regulatory efficiency by making it easier for licensees to comply.

  The rule modifies the process for making changes to QA programs, which will increase efficiency for holders of a QA program approval and the NRC oversight of QA programs. Holders of a QA program approval will not need to apply to renew their approval and the NRC will not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC will re-issue QA program approvals with no expiration date.

- **Environmental Considerations:** The amendments will expand the low-level material exemption for natural material and ores containing naturally occurring radionuclides to allow material that has been processed to qualify for the exemption. These changes will increase the number of shipments of low specific activity radioactive material that will be exempt from

the NRC and the DOT transport regulations (i.e., will not be shipped as hazardous material). The Environmental Assessment (Agencywide Document Access and Management System (ADAMS) Accession No. ML12187A109) discusses the environmental considerations in greater detail. After evaluating the potential environmental impacts, the NRC determined that there will be no significant impact to the public from the amendments.

- **NRC Operations**: Since QA program renewal applications will no longer be required, holders of a QA program approval will not need to apply to renew their approval, thereby reducing the expenditure of NRC resources needed to review such applications. With the publication of a final rule, the NRC will re-issue QA program approvals with no expiration date. The NRC will need to review the biennial reports of changes to QA programs that do not reduce commitments to the NRC. The action will result in a small annual savings to the NRC in the oversight of QA programs.

The following attributes are not expected to be affected:

Public Health (Accident)	***Offsite Property***	***Occupational Health (Accident)***
Public Health (Routine)	***Onsite Property***	***Occupational Health (Routine)***
Antitrust Considerations	***General Public***	***Safeguards and Security***
Improvements in Knowledge		

3.2 Analytical Methodology

This section describes the methodology used to analyze the benefits and costs associated with the rule. The benefits consist of any desirable changes in the affected attributes. The costs consist of any undesirable changes in the affected attributes. To the extent practical, quantitative information (e.g., costs and savings) and qualitative information on attributes affected by the rule have been identified by the NRC.

As described in Section 3.1, the attributes expected to be affected include the following:

- Industry Operation
- Industry Implementation
- NRC Implementation
- NRC Operation
- Other Governments
- Regulatory Efficiency
- Environmental Considerations

In accordance with guidance from the Office of Management and Budget (OMB) and NUREG/BR-0058, Rev. 4[2] this RA presents the results of the analysis using both 3 percent and 7 percent real discount rates. The real discounted rates or present-worth calculation simply determines how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth, costs and benefits, regardless of when averted in time, are valued equally. Based on OMB guidance (OMB Circular No. A-4, September, 17, 2003), present-worth calculations are presented using both 3 percent

[2] (http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/)

and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on longterm government debt, which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7 percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector.

The RA includes assumptions and estimates. The NRC relied on referenced sources for the assumptions and estimates when these were available.

3.2.1 General Assumptions

Costs are expressed in 2014 dollars and are modeled either on an annual recurring cost basis or on a one-time implementation basis. The RA calculates costs over a 10-year analysis period, with the annual costs in each year beyond 2014 discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, Rev. 4.

Here is a discussion of the NRC's general input assumptions for this analysis.

- The NRC labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627, Rev. 1. This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the amendments. Currently, the NRC hourly labor rate is $121.

- Licensee labor rates were determined from National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used. For all licensee labor rates, $73.20/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Nuclear Engineers."

- The NRC-determined Agreement State labor rates are based on National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used. For all Agreement State labor rates, $60.80/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Lawyers".

- The DOE hourly labor rates will match the NRC rate; i.e., $121/hour.

- The time period for the analysis is 10 years, because licenses are on a 10-year cycle for renewals.

- Estimates were made for one-time implementation costs. It is assumed that the costs will be incurred in the first year after the rule becomes effective. This will provide a conservative estimate of the one-time implementation costs, because one-time costs

that may occur later (e.g., rulemaking conducted by the Agreement States will not be discounted).

- Estimates were made for recurring annual operating expenses to support implementation of the rule. The values for annual operating expenses are assumed to be identical for each of the 10 years in the analysis. The annuity formula used to discount the annual expense values is on page B.3 of NUREG/BR-0184.

3.2.2 Specific Assumptions for Alternative 2

Under Alternative 2, the NRC will amend the domestic transport regulations to maintain compatibility with the IAEA's TS-R-1 transportation standards revised in 2009. These changes will impact licensee shipping costs as well as rulemaking costs for the Agreement States. Appendix 1 details the licensee costs for Alternative 2. The specific NRC assumptions for Alternative 2 costs are as follows:

- There are one-time costs that may be incurred in response to changes to 10 CFR Part 71.
    - It is assumed that licensees and certificate holders maintain awareness of changes to the relevant transportation regulations but will incur costs associated with this effort. It is estimated that 50 percent of licensees will obtain materials relating to training on the current requirements, with commercial references estimated to cost $60 and a total cost of $7,500.
    - It is assumed that some effort will be made to review the changes in the regulations. The rule includes 24 amendments. It is estimated that an average of 2 hours per licensee or certificate holder will be spent reviewing the changes, for a total of approximately $35,000.
- The changes to § 71.14(a) will allow some additional material and objects to be shipped under the exemption. Natural material and ore containing naturally occurring radionuclides that has been processed could be shipped without being classified as hazardous material if it meets the expanded exemption. The material will not be shipped for the use of its radionuclides. Licensees will need to ensure correct labeling and placarding for their shipments. This will require them to determine whether material can be shipped under the exemption if it is to be treated as radioactive material.
    - Because the material is not being shipped for use of its radionuclides, it is assumed that most licensees will be unaffected by this change. It is assumed that about 2 percent of licensees (5 licensees) will be affected by this change.
    - The number of DOE shipments affected is estimated to be 0.5 percent of the low-level wastes and "other" radioactive material shipments in 2004. This corresponds to approximately 6 rail shipments and 74 truck shipments.
    - The estimated annual quantity of material shipped by industry is based on the average consumption for the following: tantalite ore, niobium ore, and rare earth concentrates for the years (2006 – 2010) where consumption amounts are

available in the U.S. Geological Survey Mineral Commodity Summaries[3] after being adjusted to better approximate the amount of material affected by the change. It is also assumed that the tantalite slag and niobium slag are transported in the same quantities as tantalite ore and niobium ore, respectively.

- The fraction of tantalite ore and tantalite slag affected by the change is estimated using information from the Tantalum-Niobium International Study Center that was included in the IAEA Coordinated Research Program and the activity levels listed in "The Trade in Radioactive Materials ─ Potential Problems and Possible Solutions" by Nick Tsurikov (2008) and "Regulation of Natural Radioactivity in International Transport and Trade" by N. Tsurikov, et. al. (2006)[4]. The estimates for niobium and niobium slag assume the fraction of material less than 10 Bq/g of uranium-238 and thorium-232 are the same as that estimated by the Tantalum-Niobium International Study Center for tantalite ore and tantalite slag.

- It is assumed that the material is processed, but not for its radionuclides. Because assuming that the material, with the exception of the slag, has been processed is likely to overestimate the quantity of material evaluated that will qualify for the exemption, the volume of material and the number of shipments will include the shipment of some material not specifically evaluated.

- It is estimated that approximately 12,000 metric tons of material is shipped annually by rail in approximately 125 railroad cars (or shipments).

- It is assumed that annual fees and permits will not be affected by this change; because some material will still be shipped as class 7 (radioactive) hazardous materials.

- It is estimated that approximately $500 per shipment will be saved, because the material will not be shipped as radioactive material.

- The NRC is incorporating by reference 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."[5] The NRC is allowing the use of certain ISO tests as an alternative to the tests prescribed by 10 CFR Part 71. The NRC is allowing the use of the Class 4 and Class 5 impact tests and the Class 6 temperature test. The ISO Class 5 impact test can be used for a specimen weighing less than 500 grams. The ISO tests are more rigorous than the tests prescribed in 10 CFR Part 71, so they are not the most common tests used to qualify special form material.

    - It is assumed that each of the 250 impacted licensees will obtain a copy of the ISO standards. It is also assumed that they will acquire the standards at the non-member rate. These estimates will be conservative in estimating the costs.

[3] http://minerals.usgs.gov/minerals/pubs/mcs
[4] http://calytrix.biz/papers/07.NORM_trade.pdf
[5] (http://pbadupws.nrc.gov/docs/ML0036/ML003686268.pdf)

Purchasing the two standards from the distributor in the U.S. will cost each licensee $200 for a total cost of $50,000.

- The NRC estimates there are 60 Class 4 and 60 Class 6 tests performed per year. Although the ISO standard that includes these tests has been updated, it is assumed that no new equipment is needed to perform these tests.

- The Class 5 impact tests allow a smaller hammer to be used for smaller specimens. It is assumed that acquiring the testing equipment will cost $500 for each licensee who acquires the equipment. It is assumed that 5 licensees will purchase the equipment, for a total cost of $2,500.

- It is estimated that licensees will perform 50 Class 5 impact tests each year instead of the Class 4 impact test at an equivalent savings of the costs for one labor hour per test, for a total savings of $3,660.

- Other changes will amend certain values in 10 CFR Part 71, Tables A-1 and A-2. These changes will result in an estimated net savings of $20,000 annually for the industry.

- It is assumed that CRCPD will update Part T to the Suggested State Regulations for Control of Radiation, which addresses the requirements of 10 CFR Part 71. It is assumed that this effort will take approximately 2 FTE. It is assumed that in addition to supporting the development of the Suggested State Regulations for Control of Radiation, the Agreement States will average about 444 labor hours (0.25 FTE) each to review rule language and to amend regulations consistent with the final rule. An estimate of 19,980 labor hours for all 37 Agreement States is made and modeled as a one-time labor cost.

3.2.3 Specific Assumptions for Alternative 3

Under Alternative 3, the NRC will make the changes identified above for Alternative 2 plus other NRC-initiated changes. Appendix 2 details the additional costs for Alternative 3. The specific assumptions for Alternative 3 costs are listed below.

- The changes to 10 CFR 71.15(d) will revise the exemption that applies to 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. Within the transportation packages, the material must be distributed homogeneously and must not form a lattice arrangement, in order to qualify for the exemption. The type of material that will be affected by this change is more likely to be possessed by the DOE than by a licensee. Uranium of this enrichment is not used in commercial power reactors, and therefore is not typically shipped. Therefore, it is assumed that only the DOE will ship this material.

    - Shipments of material that will be affected by the revised exemption are expected to be infrequent – one shipment every 10 years. The NRC's cost estimate is based on this assumption, and it is further assumed that this shipment will occur midway through the analysis period.

    - Material which does not meet the revised exemption will likely be able to be shipped under a general license for fissile material, which will require the

calculation of the CSI and appropriate labeling, and on an exclusive use conveyance. It is estimated that the labor associated with determining the appropriate CSI, which involves determining the mass of fissile materials for the shipment, and labeling will take 40 hours. It is assumed that the CSI will not exceed 100, so the shipment will not need to be shipped using separate conveyances.

- The NRC is amending 10 CFR 71.38, and adding a new 10 CFR 71.106, to remove the need for QA program approvals to be renewed. These changes will result in a savings for the NRC, general licensees, and holders of, or applicants for, a CoC.

- Based on these changes, the NRC estimates there will be an average of 25 fewer QA program approval reviews each year. Holders of the QA program approval will not need to prepare a request for a renewal, because the NRC will be issuing QA program approvals that will not expire for all existing QA program approvals. It is estimated that each renewal request takes about 20 hours to prepare. The estimated total annual savings for holders of a QA program approval will be 500 labor hours (or $36,600). The NRC estimates that it averages 10 hours of effort per renewal.

- Existing QA program approvals will expire. The NRC will need to issue new QA program approvals that will not have an expiration date. The NRC estimates that issuing the replacement QA program approvals will require 40 hours to complete for a one-time NRC cost of approximately $4,800.

- The NRC is adding requirements to make it more efficient for holders of a QA program approval to make changes to their QA program that do not reduce their commitments to the NRC.

    - The new requirements in 10 CFR 71.106(a) will result in a savings for holders of a QA program approval and the NRC. Holders of a QA program approval will no longer be required to obtain prior NRC approval for changes to their QA program description that do not reduce their commitments to the NRC. The NRC estimates that 14 holders of QA program approvals will benefit from the amendments each year. It is estimated that, on average, 25 labor hours will be saved each time a QA program approval holder does not need to obtain prior NRC approval for their changes. It is estimated that the NRC takes 5 hours to review each request.

    - The new requirements in 10 CFR 71.106(b) will require that respondents periodically report changes that they made that did not reduce their commitments to the NRC. The NRC estimates 250 entities will be affected every 2 years by these new requirements. The NRC estimates that QA program approval holders will spend 1 hour every 2 years to comply with this requirement. The NRC estimates it will spend 1 hour to review each submittal.

    - Holders of a QA program approval will be required to maintain records created in response to the changes to § 71.106. The NRC estimates that each QA program approval holder will spend 0.5 hours annually to maintain these records.

- There will be a one-time labor cost for the NRC and the Agreement States to implement Alternative 3. It is assumed that implementing Alternative 3 will require 50 percent more Agreement State staff hours than the effort required to implement Alternative 2. This means about 29,970 labor hours will be required of the Agreement States. This is modeled as a one-time labor cost.

3.2.4 Data on Affected Entities

The analysis makes the following assumptions regarding the entities affected:

The NRC estimates 290 entities ─ 210 general licensees or users of packages, 40 certificate holders/applicants for certificate holders, 37 Agreement States, DOE, DOT, and CRCPD ─ will be directly affected by the amendments. The affects on the CRCPD ─ development of Suggested State Regulations for Control of Radiation ─ will be a subset of, and considered as part of, the affects on Agreement States, because it will be Agreement State staff working to develop the Suggested State Regulations for Control of Radiation.

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 quality assurance program description issued under 10 CFR parts 50, 71, or 72; and holders of a certificate of compliance for a transportation package. These companies do not 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, "NRC size standards."

4. PRESENTATION OF RESULTS

This section presents results of benefits and costs that are expected to be derived from the rule. The results are shown for each of the following attributes:

- Industry Operation
- Industry Implementation
- NRC Implementation
- NRC Operation
- Other Government Implementation (Agreement States)

The rule is expected to provide benefits in Regulatory Efficiency and Environmental Considerations, but these are not quantified because they are expected to be small.

The quantified benefits are presented in constant 2014 dollars, for both implementation and annual operating expenses. The impact of the rule over a 10-year analysis period is estimated using 3 percent and 7 percent real discount rates to show an overall effect in terms of 2014 dollars. Alternative 1, the No-Action Alternative, provides a baseline against which the other two alternatives are assessed. The baseline assumes full compliance with existing NRC requirements. This baseline is consistent with NUREG/BR-0058, which states that, "in evaluating a new requirement...the staff should assume that all existing NRC requirements have been implemented."

4.1 Summary of Results

This section presents results of the benefits and costs that are expected to be derived from the rule. To the extent that the affected attributes could be analyzed quantitatively, the costs have been calculated and are presented below. Some benefits and costs are addressed qualitatively for reasons discussed in Section 3.1.

Table 4-1 presents the net impact of the rule for each of the three alternatives, at 3 percent and 7 percent real discount rates, including all benefits and costs over the 10-year analysis period. A positive value for net impact is a cost.

Table 4-1: Net Impact of Alternatives 1, 2, and 3

3 percent discount rate		7 percent discount rate	
Alternative 1	$0	Alternative 1	$0
Alternative 2	$766,887	Alternative 2	$862,799
Alternative 3	$776,916	Alternative 3	$979,176

There are no costs or benefits associated with Alternative 1, the No Action Alternative. The estimated cost of approximately $0.8 million (3 percent discount rate) for Alternative 2 is to implement the rule in NRC and Agreement State regulations as well as a small industry shipping savings.

Alternative 3 includes the costs in Alternative 2 and the NRC initiated changes resulting in a small overall cost savings over the 10-year analysis period. The major contributing costs and benefits under Alternative 3 are as follows:

- The removal of the requirement to submit QA related information to the NRC, which equals to an annual industry savings of approximately $50,000.

- As a result of removing the requirements to submit QA information, the NRC will save approximately $20,000 annually in operating expenses.

Because of the larger scope of activity, the cost to the Agreement States to implement amended regulations is about 50 percent higher for Alternative 3 compared to Alternative 2.

Table 4-2 shows the estimated costs and benefits, by attribute, over the 10-year analysis period for Alternative 1, 2, and 3 at a three and seven percent discount rate.

Table 4-2: Estimated Benefits and Costs by Attribute for Alternative 1, 2 and 3

3% Discount Rate	Alternative 1	Alternative 2	Alternative 3
Industry Implementation	$0	$95,136	$95,136
Industry Operation	$0	-$543,033	-$954,207
NRC Implementation	$0	$0	$4,760
NRC Operation	$0	$0	-$190,949
Agreement States	$0	$1,214,784	$1,822,176
Total	$0	$766,887	$776,916

7% Discount Rate	Alternative 1	Alternative 2	Alternative 3
Industry Implementation	$0	$95,136	$95,136
Industry Operation	$0	-$447,121	-$785,673
NRC Implementation	$0	$0	$4,760
NRC Operation	$0	$0	-$157,223
Agreement States	$0	$1,214,784	$1,822,176
Total	$0	$862,799	$979,176

Table 4-3 summarizes the costs by entity, over a 10-year analysis period. Appendices 1, 2 and 3 give details to the results presented in Table 4-2

Table 4-3: Summary of Benefits and Costs for Alternatives 2 and 3

Alternative 2

	One-time Implementation Costs	Annual Operating Costs	Total Combined Implementation and Annual Cost for 10-year period at 3%	Total Combined Implementation and Annual Cost for 10-year period at 7%
Industry Costs	$95,136	-$63,660	-$447,897	-$351,985
Agreement States	$1,214,784	$0	$1,214,784	$1,214,784
NRC Costs	$0	$0	$0	$0
Total	$1,309,920	-$63,660	$766,887	$862,799

Alternative 3

	One-time Implementation Costs	Annual Operating Costs	Total Combined Implementation and Annual Cost for 10-year period at 3%	Total Combined Implementation and Annual Cost for 10-year period at 7%
Industry Costs	$95,136	-$111,862	-$859,071	-$690,537
Agreement States	$1,822,176	$0*	$1,822,176	$1,822,176
NRC Costs	$4,760	-$22,385	-$186,189	-$152,463
Total	$1,922,072	-$134,247	$776,916	$979,176

*****Agreement States do not have annual operating cost saving because NRC reviews the QA program

4.2 Backfitting

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 contain 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.

5. DECISION RATIONALE

There is a need to amend the NRC's regulations to achieve compatibility with the IAEA's TS-R-1 safety standards. The assessment of costs and benefits discussed above leads the NRC to the conclusion that this final rule will improve regulatory efficiency and effectiveness for transportation of radioactive material, and will be cost-beneficial to the NRC and industry. The final rule is expected to slightly reduce impacts to public health and safety.

Three alternatives were evaluated in this RA. Alternative 1 would take No Action and would maintain the regulations as currently written.

Alternative 2 would amend regulations to provide compatibility with the IAEA's TS-R-1 safety standards and with changes made by the Amending the NRC's regulations can be done through rulemaking with a one-time implementation cost to the NRC, Industry, and the Agreement States equal to about $1.3 million, followed by an annual operating cost savings of approximately $64,000.

Alternative 3 would amend NRC regulations as described in the *Federal Register* notice that has been prepared for the final rule. These amendments would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency as well as make small improvements to public health and safety. The implementation cost would be approximately $1.9 million, followed by an annual savings to industry of an estimated $134,000 (in 2014 dollars). The NRC has determined that Alternative 3 is superior to the other two alternatives, and improves regulatory efficiency.

6. IMPLEMENTATION

Compliance with the amendments adopted in the NRC's final rule is required beginning July 13, 2015. However, the Agreement States have 3 years from the effective date of the final rule to adopt compatible regulations.

7. REFERENCES

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Appendix 1 Alternative 2 Licensee costs

Citation	Description	Number Licensees	Annual Responses	Cost per Shipment/Hours Per Response	Annual hours per change	Total Annual Cost	One Time Cost	Total 10 Year 3% NPV	Total 10 Year 7% NPV
71.14(a)	Natural material/ore could be shipped without being classified as hazardous material if it meets the expanded exemption.	5	80	-500		-$40,000		-$341,208	-$280,943
	Purchase copy of ISO standards.	250					$50,000		
	Maintain awareness of changes to the relevant transportation regulations.						$7,500		
	240 licensees will need to read the new regulations and will determine actions necessary	240	240	2	480		$35,136		
71.75(d)	Will incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and will allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams.	50	-50	1	-50	-$3,660	$2,500	-$31,221	-$25,706
Appendix A	Shipment cost savings detailed below					-$20,000	$0	-$170,604	-$140,472
	Total Alternative 2					-$63,660	$95,136	-$543,033	-$447,121
							+one time cost	$95,136	$95,136
							TOTAL	-$447,897	-$351,985

Shipment Cost Savings

Change	Truck shipments/year	Discussion and Basis for Estimates	Licensee cost or savings to comply with transportation regulations ($/ truck shipment)	Annual Cost of shipments (2014$)
Table A-1				
Cf-252	5		(500)	(2,500)
Kr-79	25		(500)	(12,500)
Table A-2		-		
Kr-79	25	-	(100)	(2,500)
Te-121m	25	-	(100)	(2,500)
Totals		-		(20,000)

Appendix 2: Alternative 3 Costs

Licensee

Citation	Description	Number Licensees	Annual Responses	Hours Per Response	Annual hours per change	Total Annual Cost	One Time Cost	Total 10 Year 3% NPV	Total 10 Year 7% NPV
71.15(d)	*Revises the exemption that applies to uranium enriched to a maximum of 1 percent.	1	0.1	40	4	$293	$0	$2,498	$2,057
71.38(c)	Renewal of a CoC will be revised to remove references to renewals of QA program approvals, which will no longer be necessary.	25	-25	20	-500	-$36,600	$0	-$312,205	-$257,063
71.106(a)	Allows certificate holders and applicants for a COC to make changes to their approved QA program if the changes do not reduce the commitments in the QA program previously approved by NRC.	14	-14	25.00	-350	-$25,620	$0	-$218,544	-$179,944
71.106(b)	Changes to quality assurance program. Added to revise the process for obtaining NRC approval to make changes to an approved quality assurance program and to report to the NRC those changes that do not require prior NRC approval	250	125	1.00	125	$9,150	$0	$78,051	$64,266
71.135	Recordkeeping	250	125	0.5	63	$4,575	$0	$39,026	$32,133
							$95,136		
						-$111,862	**TOTAL**	-$954,207	-$785,673
							+ one-time costs	$95,136	$95,136
	Total Alternative # 3						**TOTAL**	-$859,071	-$690,537

[1] Note Alternative 3 includes all cost and benefits for “Alternative 2” in Appendix 1.

NRC Alternative # 3

Citation	Description	Number Licensees	Response Per Year	Total Annual Responses	Labor Hours Per Response	Total Annual Costs	One Time Cost Per	Total 10 Yr 3 Percent NPV	Total 10 Yr 7 percent NPV
71.38	Issue new QA program approvals.	240	0	0	0.17	$0	$4,760	$4,760	$4,760
71.38(c)	Review renewals of QA program.	24	(1)	(24)	10	-$29,040	$0	-$247,717	-$203,965
71.106 (a)	Holders of a QA Program Approval will no longer be required to obtain prior NRC approval of changes to their QA program description that do not reduce their commitments to the NRC.	14	(1)	(14)	5	-$8,470	$0	-$72,251	-$59,490
71.106(b)	Report to the NRC those changes that do not require prior NRC approval.	125	1	125	1	$15,125	$0	$129,019	$106,232
							Total One Time Cost		
							$4,760		
						-$22,385	**TOTAL**	$186,189	$152,463

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR THE FINAL RULE AMENDING 10 CFR PART 71

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

Office of Federal and State Materials and Environmental Management Programs

U.S. Nuclear Regulatory Commission

September 2014

I. THE PROPOSED ACTION

The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is amending its requirements for the packaging and transportation of radioactive material in Part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR). Some of the amendments will make conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) regulations for the international transportation of radioactive material. More specifically, these changes will make the NRC's regulations compatible with the 2009 edition of the IAEA's transportation standard, "Regulations for the Safe Transport of Radioactive Material" (TS-R-1), and maintain consistency with changes that the DOT has made in its regulations in response to TS-R-1. This part of the rulemaking harmonizes the NRC's regulations with the IAEA's transportation standards in TS-R-1, and aligns with the DOT's regulations, as revised in July 2014.

Other amendments, initiated by the NRC, will:

1. Revise a provision that exempts some shipments of fissile material from transportation package requirements. For shipments of uranium enriched to a maximum of 1.0 weight percent U-235, the exemption is revised to require that this fissile material be distributed

homogeneously within its transportation package and not form a lattice arrangement.

2. Clarify the responsibilities of certificate holders and licensees when making preliminary determinations.

3. Revise quality assurance program regulations to a) add provisions to allow changes to approved quality assurance programs that do not reduce commitments made to the NRC to be implemented without prior NRC approval, and b) implement a change in practice where quality assurance program approvals would not expire.

II. THE NEED FOR THE PROPOSED ACTION

The IAEA is chartered to establish safety standards to protect public health and safety and to minimize the danger to life and property and has developed international safety standards for the safe transport of radioactive material in TS-R-1. By providing a global framework for the consistent regulation of the transport of radioactive material, TS-R-1 facilitates international commerce and contributes to the safe conduct of international trade involving that material.

Periodically, the IAEA revises its standards related to transportation of radioactive material. The NRC evaluated changes in the 2009 edition of the IAEA's 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 standards.

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.

As indicated above, another set of amendments, initiated by the NRC, revise 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 determinations; and 5) make editorial revisions to correct and clarify certain other requirements.

III. ENVIRONMENTAL IMPACTS OF PROPOSED ACTION

The proposed action consists of a number of changes to 10 CFR Part 71. Many of these changes fall within the categorical exclusions listed in § 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review" within 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Regulatory Functions." The Commission has previously determined that such actions, neither individually nor cumulatively, would have significant impacts on the human environment and the environmental impacts of these changes are not evaluated in detail in this environmental assessment.

The proposed action consists of a number of changes that do not fall within the categorical exclusions listed at 10 CFR 51.22, which are evaluated as part of this environmental assessment. The following table identifies these changes and the section of the environmental assessment in which they are described in more detail and their environmental impacts are discussed.

Table 1: Proposed Changes Evaluated in the Environmental Assessment

Section	Subject	Proposed Changes	Analysis
71.4	Definitions	Add definition of "contamination."	See Section III.A.
71.4	Definitions	Revise definition of "Criticality Safety Index (CSI)."	See Section III. A.
71.4	Definitions	Revise definition of "Low Specific Activity (LSA) material."	See Section III.A.
71.4	Definitions	Revise definition of "special form radioactive material."	See Section III.A.
71.4	Definitions	Revise definition of "uranium – natural, depleted, enriched."	See Section III. A.
71.14	Exemption for low-level materials	Revise paragraph (a), add paragraph (a) (3).	See Section III.B.
71.15	Exemption from classification as fissile material	Revise paragraph (d).	See Section III.C.
71.70	Incorporation by reference	Add a section that consolidates incorporation by reference language.	See Section III.D.
71.75	Qualification of special form radioactive material	Revise paragraphs (a) (5) and (d).	See Section III.D.
Appendix A, Table A-1	A_1 and A_2 Values for Radionuclides	Add an entry for Kr-79. Revise the A_2 value for Cf-252.	See Section III.E.
Appendix A, Table A-2	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides	Revise entry for Te-121m and add entry for Kr-79.	See Section III.E.

A. Revised Definitions

Description of the Change: The definition for "Contamination" is added to § 71.4 to be consistent with the definition in the DOT transportation regulations at 49 CFR Part 173 and IAEA's TS-R-1. The definition of "Criticality Safety Index (CSI)" is revised to be consistent with the definition in the DOT's regulations at 49 CFR Part 173 and IAEA TS-R-1 by addressing overpacks and freight containers in the definition. The definition of "Low Specific Activity (LSA) material" is revised to be consistent with the definition in the DOT's regulations at 49 CFR Part 173 and IAEA's TS-R-1 by making the description of LSA material apply to material which is intended to be processed for the use of the uranium, thorium, and other naturally occurring radionuclides. The definition of "Special form radioactive material" is 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 radioactive material. The definition of "Uranium — natural, depleted, enriched" is revised by adding "(which may be chemically separated)" to the portion of the definition that describes natural uranium. This portion of the definition becomes "[n]atural 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)."

Environmental Impacts of the Change (included in the Proposed Action and Alternative 2): The changes to the definitions of "Criticality Safety Index (CSI)" and "Uranium — natural, depleted, enriched" provide clarifications. Because the change to the definition of CSI incorporates overpacks and freight containers but does not change how the CSI is calculated; this change will not have any environmental impacts. The change to the definition of "Uranium -- natural, depleted, enriched" does not alter the distributions of uranium isotopes used to describe the "Uranium—natural, depleted, enriched." Also, whether or not the material is chemically processed does not change the scope of material that falls within the definition and

does not affect any of the other definitions where “Uranium—natural, depleted, enriched” is used.

The change in the definition of “Low Specific Activity (LSA) material” corrects the “LSA-I” component of this definition. Specifically, existing subsection (1)(i) of the “Low Specific Activity (LSA) material” definition includes the word “not.” This makes the NRC definition inconsistent with the DOT definition of LSA material (which does not include the word “not”). Removal of the word “not” makes the NRC definition for LSA material consistent with the DOT definition in 49 CFR 173.403, which has been in effect since October 1, 2004. The DOT definition is consistent with the IAEA’s transportation standards and is the definition that has been used in practice. Thus, there will be no impact (radiological or non-radiological) from this change, because licensees are already using the DOT definition.

The environmental impacts associated with adding the definition of “contamination” would be from the transportation of certain non-radioactive solid objects with radioactive substances present on any surface that would now qualify for the low-level material exemption. These impacts are evaluated in Section III.B.

The changes to the definition of “Special form radioactive material” allow material already tested to continue to qualify as special form radioactive material. Because the changes allow the continued use of Special form radioactive material that has been qualified using current tests and do not change the requirements applicable to this qualified material, there are no environmental impacts associated with this change. The testing allowed under the International Organization for Standardization (ISO) tests that are proposed to be added to § 71.75(d) are no less stringent than the existing tests. The impacts associated with the changes to the ISO tests are discussed in Section III.D.

Environmental Impacts for No Change (No Action Alternative): There are no environmental impacts associated with the no-action alternative. Not making the changes to the definitions of CSI, "Uranium ─ natural, depleted, enriched," and LSA would not result in environmental impacts.

The environmental impacts from not changing the definition of "Contamination" are evaluated in Section III.B.

The environmental impacts from not changing the definition of "Special form radioactive material" arise from the tests used and these impacts are discussed in Section III.D.

B. Changes to the Exemption for the Shipping of Low-Level Radioactive Material

Description of the Change: The exemption that allows some natural materials and ores containing naturally occurring radionuclides to be transported without being handled as hazardous material is changed to indicate that such natural material or ore could be in either its natural state or have been processed. The exemption is also changed to specifically allow non-radioactive solid objects with "contamination" to be transported without being handled as hazardous material.

Environmental Impacts from the Change (included in the Proposed Action and Alternative 2): The low-level material exemption applies to material that presents a very low hazard and has an activity concentration that does not exceed 10 times the values specified in 10 CFR Part 71, Appendix A, Table A-2 ("Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material: Safety Guide" (TS-G-1.1), IAEA, 2002). The transportation regulations that apply to the material that are included within the scope of the low-level material exemption for natural materials and ores include requirements on shipping papers, packaging, package marking, labeling, preparation of the shipment of the material, and transport vehicle placarding related to the shipment and transportation. The change will allow

some additional material to qualify for the exemption, because the change explicitly allows material that has been processed to qualify for the exemption. Although material that qualifies for the exemption under the change is exempted from these requirements, these requirements do not significantly affect the radiological exposures associated with the shipment and transportation of such low-hazard material.

Under normal conditions of transport, the impacts primarily involve radiation exposure. However, there is a potential for environmental contamination arising from accidents, cargo shifts, package failures, loading, unloading, and handling problems for the natural materials and ores affected by this change. The dose criteria used in determining the activity concentrations for exempt material ensure that the doses (from either single or multiple sources) do not reach unacceptable levels and will be far below the public dose limits. The dose criteria consider both normal conditions and accident conditions (i.e., an individual effective dose of 10 μSv/year (1 mrem/year) for normal conditions and a collective dose of 1 person-Sv/year (100 person-rem/year) for normal conditions; 1 mSv (100 mrem) for an individual effective dose for accident conditions; and 50 mSv (5 rem) for an individual dose to the skin for both normal and accident conditions) (TS-G-1.1)). In addition, the impacts from events that result in releases can be significantly reduced through prompt clean-up.

The low-level material exemption is amended to allow non-radioactive solid objects with radioactive substances present on any surfaces in quantities that do not exceed the levels in the definition for contamination. The derivation of the limits defining the level of contamination and the potential impacts from contamination are discussed in TS-G-1.1. Non-fixed contamination can contribute to external, ingestion and inhalation exposures, and can spread, whereas fixed contamination would only contribute to external exposures. Contamination below the values in the definition would only contribute to insignificant exposures through inhalation, ingestion, or external exposure. The derived values are conservative with respect to transportation. As a

result, this change would have, at the most, small radiological and non-radiological impacts.

Activity concentrations that are 10 times the activity concentration for exempt material were established in TS-R-1 for naturally occurring materials and ores to avoid applying the transport regulations to enormous quantities of material that present a very low hazard (TS-G-1.1). The factor of 10 is intended to provide a balance between radiological protection concerns and the burden associated with the regulation of very large quantities of material. These activity concentrations ensure that the doses for both normal and accident conditions remain well below the public dose limits for normal and accident conditions.

The exemption, which also appears in the DOT's regulations, already covers many types of material from mining and minerals processing, building materials, and other natural materials. Large quantities of these materials are currently transported under the current exemption. Because they do not involve activities licensed by the NRC, they are not subject to the NRC's transportation regulations. The regulatory burden associated with these shipments is small and include requirements on shipping papers, packaging, package marking, labeling, preparation of the shipment of the material, and transport vehicle placarding related to the shipment and transportation. Material that is categorized by the DOT as Class 7 (radioactive) material could incur additional expenses and restrictions that would add to the cost of transportation that could influence the shipping modes and routes used to transport the material. Although the relative savings will depend on the relative value of the material, it is generally less than the monthly variability in the value of the material. Because the reduction in transportation costs and regulatory burden from the proposed amendment is small relative to the value of the material most likely to qualify under this expanded exemption, the changes are not expected to significantly increase the amount of material that is being shipped.

The IAEA conducted a coordinated research program to inform decisions about the amount of regulatory control that may be appropriate for the transportation of natural material

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

In summary, the environmental impacts associated with the proposed changes to the low-level material exemption are expected to be small and not significant. Removing the regulatory controls for transporting this material will not lead to substantially higher radiological exposures, because the applicable regulations do not substantially increase the radiological exposures from these materials and the proposed amendment is not expected to significantly increase the amount of material being transported. The preliminary results of the Coordinated Research Program indicate that radiological exposures will remain small and well below unacceptable levels and public dose limits for both normal conditions and accident conditions. Environmental impacts associated from accidental releases are expected to be very small and

amenable to prompt clean-up. The impacts from allowing non-radioactive solid objects with radioactive substances present on surfaces in quantities below that used to define contamination are expected to be small.

Environmental Impacts for No Change (No Action Alternative): The dose criteria used in determining the activity concentrations for exempt material under the existing exemption ensures that the doses (from either single or multiple sources) do not reach unacceptable levels and would be far below the public dose limits. These criteria consider both normal conditions and accident conditions (i.e., an individual effective dose of 10 μSv/year (1 mrem/year) for normal conditions and a collective dose of 1 person-Sv/year (100 person-rem/year) for normal conditions; 1 mSv (100 mrem) for an individual effective dose for accident conditions; and 50 mSv (5 rem) for an individual dose to the skin for both normal and accident conditions) (TS-G-1.1)). Therefore, the existing low-level material exemption applies to material that would not result in unacceptable high doses (from either single or multiple sources) and the doses would be far below the public dose limits when considering both normal and accident conditions.

There would not be any changes to the material that could qualify for the low-level material exemption, if the changes are not made. Without the changes, the material would not qualify for the exemption and would continue to be transported as the DOT Class 7 (radioactive) material. Class 7 (radioactive) material may, depending on the routing and mode of transport, be subject to additional fees and restrictions. To avoid these additional fees or other restrictions, the Class 7 material may be transported over longer routes than similar material that does qualify for the current low-level material exemption. As a result, not changing the low-level material exemption may result in small impacts from the longer transportation routes.

Transporting non-radioactive solid objects with radioactive substances present on any surfaces in quantities that do not exceed the levels in the definition of contamination would only contribute to insignificant exposures through inhalation, ingestion or external exposure and

would not cause environmental contamination. The regulations that apply to the transportation of these non-radioactive solid objects do not significantly affect the radiological exposures, which are insignificant, or environmental contamination. Therefore, the impacts for making no change to the treatment of these non-radioactive solid objects would be similar to the impacts if the change were made.

C. Prohibition on Heterogeneous Distribution and Lattice Arrays for Shipping Fissile Material Under the Exemption in § 71.15(d)

Description of the Change: The NRC is revising § 71.15(d) criteria that, if satisfied, will exempt certain material from being classified as fissile material and from the fissile material package standards in §§ 71.55 and 71.59. The NRC is further restricting the exemption for uranium enriched with uranium-235 to a maximum of one percent by weight to fissile material that is homogeneously distributed and does not form a lattice-like arrangement (i.e., is not in a fixed, repeating configuration such as found in a nuclear fuel assembly).

Environmental Impacts of the Change (Included in the Proposed Action): The change would ensure that material containing uranium enriched in uranium-235 to a maximum of one percent by weight and qualifying for the fissile material exemption under § 71.15(d) is subcritical and criticality is not a potential hazard for this material during transportation. The fissile material that no longer qualifies for the fissile material exemption would be shipped using the fissile material package standards of §§ 71.55 and 71.59. The 10 CFR 71.15(d) exemption language continues to exclude large quantities (less than five percent of the uranium mass) of low-absorbing moderators (beryllium, graphite, or hydrogenous material enriched in deuterium). Restricting the exemption's scope will reduce the likelihood of criticality associated with transporting this material; consequently, the environmental impacts associated with this material becoming critical during transport are reduced. If a criticality occurred, the consequences would

include increased heat, increased radiation, and the formation of fission products, leading to increased radiation exposures and possible environmental contamination. Reducing the likelihood of criticality further decreases the likelihood of increased radiation exposures and environmental contamination from inadvertent criticality of material transported under the fissile material exemption.

Environmental Impacts for No Change (No Action Alternative): Similar to the proposed action, under the no-action alternative there would be a smaller margin on criticality. If criticality occurred, the consequences would include increased heat, increased radiation, and the formation of fission products, leading to increased radiation exposures and possible environmental contamination. Because the fissile material exemption provision would not change, the likelihood of criticality associated with transporting this material would remain the same, as would the consequences.

D. Incorporation by Reference and Qualification of Special Form Radioactive Material

Description of the Change: The NRC is allowing the Class 5 impact tests prescribed in the 1999 edition of the consensus standard ISO 2919, "Radiation protection – Sealed radioactive sources – General requirements and classification," to be used for specimens weighing less than 500 grams, as an alternative to the impact and percussion tests prescribed in § 71.75. This will make the NRC requirements consistent with TS-R-1 and the proposed DOT requirements. The NRC is also updating the Class 4 impact test and the Class 6 temperature test prescribed in the 1980 edition of the consensus standard ISO 2919, "Sealed Radioactive Sources – Classification," to be used for specimens weighing less than 200 grams, to the Class 4 impact test and Class 6 temperature test, respectively, prescribed in the 1999 edition. The NRC is updating the alternate leak test method prescribed in the 1979 edition of the consensus standard ISO/TR4826, "Sealed Radioactive Sources ─ Leak Test Methods," to those

leak test methods prescribed in the 1992 edition of the consensus standard ISO 9978 "Radiation protection – Sealed radioactive sources – Leakage test methods." The ISO/TR4826 has been withdrawn by the ISO and replaced by ISO 9978. This change will make 10 CFR Part 71 consistent with the DOT requirements at 49 CFR Part 173, which incorporated by reference ISO 9978:1992(E). The NRC is continuing to allow sources tested using the allowed tests in ISO/TR4826:1979(E) or ISO 2919:1980(E) to be used.

Environmental Impacts of the Change (Included in the Proposed Action and Alternative 2): Special form radioactive material is resistant to breaking from impacts or bending and resistant to melting or dispersal when subjected to heat and is a minimal contamination hazard. The changes update the alternate impact, percussion, and leak tests to more current consensus standards, which are more stringent than the existing tests. Material passing the more stringent consensus standard tests may be more robust in the event of an accident than material that passes the less stringent tests, which would result in smaller environmental impacts. The effect of these changes is expected to be a small reduction in the environmental impacts, because: 1) special form radioactive material is often tested using the tests specified in TS-R-1, which are included in 10 CFR Part 71; 2) existing tests are sufficient to ensure that the special form radioactive material is resistant to breaking from impacts or bending and resistant to melting or dispersal when subjected to heat; and 3) material passing the revised alternate tests would have been more stringently evaluated, and potentially more robust, than material tested using the tests that are being replaced. The Class 5 impact test, if used, would replace other similar and available tests. The Class 5 impact test maintains the requirement that the mass of the hammer used in the test is greater than 10 times the mass of the specimen and would be more stringent than the tests specified in TS-R-1. The change to allow the Class 5 impact test to be used would have a small environmental impact, because material qualified using the Class 5 impact test would still present a minimal contamination hazard.

Environmental Impacts for No Change (No Action Alternative): The tests used to qualify special form radioactive material would not change under the no action alternative. The more stringent tests in ISO 2919:1999(E) and ISO 9978:1992(E) would not be available for use to qualify special form radioactive material. Because the tests in ISO 2919:1980(E) and ISO/TR4826:1979(E) are not recognized as being incorporated by reference, tests in these consensus standards could not be used by NRC licensees without an exemption. There could be small negative impacts if these changes are not made because special form radioactive material tests that are included in the current 10 CFR Part 71 are less stringent than the tests in the updated consensus standards.

E. Changes to Appendix A, Determination of A_1 and A_2

Description of the Change: The NRC is adding an entry for krypton-79 (Kr-79) in Table A-1, "A_1 and A_2 Values for Radionuclides," in Part 71, Appendix A, and Table A-2, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides," in Part 71, Appendix A. The NRC is discontinuing the use of an A_2 value for californium-252 (Cf-252) in footnote h to Table A-1, "A_1 and A_2 Values for Radionuclides," in Part 71, Appendix A, that applies for domestic transportation. The A_2 value for Cf-252 in Table A-1 will instead be used for domestic transportation. The NRC is changing the total consignment activity limit for exempt consignment for tellurium-121m (Te-121m) from $1x10^5$ Bq ($2.7x10^{-6}$ Ci) to $1x10^6$ Bq ($2.7x10^{-5}$ Ci) in Table A-2 in Part 71, Appendix A.

Environmental Impacts of the Change (Included in the Proposed Alternative and Alternative 2): Kr-79 is not listed in Table A-1 in Part 71, Appendix A, and the values from Table A-3, "General Values for A_1 and A_2," in Part 71, Appendix A, are currently used to determine the A_1 and A_2 values of Kr-79. In Appendix A to Part 71, Table A-1, the A_2 value in the table for Cf-252 is updated to $3x10^{-3}$ TBq ($8.1x10^{-2}$ Ci) to be consistent with the IAEA's values in TS-R-1.

The A_1 and A_2 values are used for determining which type of package must be used for the transportation of radioactive material. The A_1 values are the maximum amount of special form material allowed in a Type A package. The A_2 values are the maximum activity of normal form radioactive material allowed in a Type A package. The A_1 and A_2 values are also used for several other packaging limits throughout TS-R-1, such as specifying Type B package activity leakage limits, low-specific activity limits, and excepted package contents limits. The values of A_1 and A_2 have been adopted in 10 CFR Part 71 and are specified in Appendix A.

The A_1 and A_2 activity concentrations are derived using the radiological consequences of accidents that result in the failure of the package and allow for multiple packages to be transported within the same conveyance. The basic radiological criteria for determining A_1 and A_2 values in TS-R-1 are:

- The effective or committed effective dose to a person exposed in the vicinity of a transport package following an accident should not exceed a reference dose of 50 mSv (5 rem).
- The dose or committed equivalent dose received by individual organs, including the skin, of a person involved in the accident should not exceed 0.5 Sv (50 rem), or in the special case of the lens of the eye, 0.15 Sv (15 rem). It is assumed that a person is unlikely to remain at a distance of 1 meter from the damaged package for more than 30 minutes.

The effective dose is the sum of the products of the dose equivalent to the organs or tissues and the weighting factors applicable to each of the body organs or tissues that are irradiated. The committed effective dose is the sum of the products of the weighting factors applicable to each of the body organs or tissues that area irradiated and the committed dose equivalent to these organs or tissues. The values of committed effective dose in the IAEA's safety standards are based on, and consistent with, the relevant International Commission on Radiological Protection (ICRP) publications, and the committed dose equivalent is the dose to some specific organ or tissue of reference that will be received from an intake of radioactive

material by an individual during the 50-year period ─ or, for children, 70-year period ─ following the intake.

The Kr-79 values added to Table A-1 are larger than the values derived using the generic values in Table A-3. This change would allow higher activities of Kr-79 to be shipped in a Type A package than would be allowed using the generic values in Table A-3 because the radionuclide-specific hazard is less than that assumed with the generic values. Although the calculated risk is the same, the actual risk per package will increase with the amount of material that is allowed to be shipped. This results from the risk being overestimated when establishing the generic values. The A_2 value for Cf-252 that would apply to domestic transportation is increasing, which allows for higher activities of normal form Cf-252 to be shipped in a Type A package than are allowed in the A_2 value in the current footnote h to Table A-1. The new values are derived using the "Q [quantity]-system" described in Appendix I of TS-G-1.1, which considers a potential exposure ─ an exposure that is not expected to occur with certainty, but may result from an accident at a source or from an event or a sequence of events ─ to develop the quantity values for A_1 and A_2. For a Type A package, the content limits (A_1 and A_2) are established to ensure that unacceptable radiological consequences do not occur, even in cases where significant damage to the package occurs. In the Q-system, a smaller radionuclide-specific hazard corresponds to a larger quantity that would result in the same potential exposure. Although the generic values for Kr-79 are being replaced by radionuclide-specific values, the dose standards underlying the A_1 and A_2 values for Kr-79 have not changed. The dose standards underlying the A_2 value for Cf-252 are the same as that used for the A_2 values for other radionuclides.

In studies of the performance of Type A packages in transportation in the United States (Finley, N.C., McClure, J.D., Reardon, P.C., Wagler, M., "An analysis of the consequences of accidents involving shipments of multiple Type A radioactive material packages," PATRAM 89

(Proc. Symp. Washington, DC, 1989), Oak Ridge National Laboratory, Oak Ridge, TN (1989)) and the United Kingdom (Gelder, R., Mairs, J.H., Shaw, K.B., "Radiological impact of transport accidents and incidents in the UK over a twenty year period," Packaging and Transportation of Radioactive Materials, PATRAM 86 (Proc. Symp. Davos, 1986), IAEA, Vienna (1986)), there was information on 22 accidents involving consignments of multiple Type A packages. The studies covered about 20 years of data. Of the 22 accidents involving multiple Type A packages, there was a release of material in only 2 of the accidents. In each of these cases, the release was on the order of 10^{-4} times the A_2 value. The likelihood of releases of these radionuclides would not change as a result of these proposed changes. Shipments of Cf-252 and Kr-79 comprise a very small fraction of shipments of radionuclides. Based on the experience documented in the studies above, releases in the event of an accident involving shipments of these radionuclides from a Type A package could be on the order of 10^{-4} times the A_2 value (or 3.0×10^{-7} TBq (8.1×10^{-6} Ci) for Cf-252 or 2.0×10^{-4} TBq (5.4×10^{-3} Ci) for Kr-79)). Uncommon releases of this magnitude would result in small impacts, which would be further reduced through clean-up. The impacts from the changes in the A_1 and A_2 values as a result of the corresponding changes in the other packaging limits that are based on these values would also be small.

The radiological consequences (environmental impacts) of these changes would be small. Krypton is a noble gas and Kr-79 has a half-life of 35 hours, so there would be no long-term impacts or contamination. The primary impacts would be a short-term increase in possible exposures in the vicinity of the package. In cases of an accident, containment, atmospheric turbulence effects, possible plume rise effects when a fire is involved, and air exchange when the accident occurs indoors will contribute to smaller exposures at further distances from the package. The Q-system assumes doses occur 1 meter from the damaged package over a 30 minute period (see TS-G-1.1).

The exemption values for total activity in TS-R-1 were established for the transportation of small quantities of material which, when transported together, are unlikely to result in any significant radiological exposure consistent with the basis for exemption in the IAEA's Basic Safety Standards[1] (i.e., an individual effective dose of 10 μSv/year (1 mrem/year) for normal conditions and a collective dose of 1 person-Sv/year (100 person-rem/year) of practice for normal conditions). Krypton-79 is not currently listed in Table A-2 in Appendix A, and the values from Table A-3 in Appendix A are used to determine the activity concentration for exempt material and the activity limit for exempt consignment for Kr-79. The radionuclide-specific exemption values proposed for Kr-79 will replace the generic values in Table A-3 and are consistent with the objectives of the exemption values. 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. Therefore, the environmental impacts from these changes will be small and insignificant, because the changes involve the transportation of small quantities of material which, when transported together, are unlikely to result in any significant radiological exposure (TS-G-1.1).

Environmental Impacts for No Change (No Action Alternative): The proposed changes to the A_1 and A_2 values and the exemption values are small. By not making the changes, the A_1 and A_2 values for Cf-252 and Kr-79 and the exemption values for Te-121m would be inconsistent with those used by other nations. This could hinder the international transportation of these materials. Differences in domestic and international regulations can make it more complicated to ship material internationally because both sets of requirements must be met. This generally makes it more expensive to import or export radioactive material. Making no change to the values would have no environmental impacts. The generic values in Table A-3 that are currently used for Kr-79 are smaller than the proposed A_1 and A_2 values and the A_2

[1] (http://www-pub.iaea.org/MTCD/publications/PDF/p1531interim_web.pdf)

value for Cf-252 that applies to domestic transportation is smaller than the proposed A_2 value. Consequently, smaller quantities of Kr-72 and normal form Cf-252 currently can be shipped in a Type A package than is allowed by the change. Under the no action alternative, the maximum quantity of material available for release from a package is proportionally smaller than the maximum quantity available for release from a package under the proposed action. As discussed above, the releases from the two accidents involving a shipment of multiple Type A packages and a release of material over 20 years of data were on the order of 10^{-4} times the A_2 value.

F. Summary of Environmental Impacts Associated with the Proposed Action

The environmental impacts associated with the proposed action have been evaluated, as described above. The environmental impacts of the changes are small when considering routine conditions of transportation and the effects of transportation accidents. The primary effects from the proposed action will be in the form of radiological exposure; however, the changes are small and generally address quantities of materials that pose little risk during either routine conditions of transportation or in cases of accidents. The changes to the risk from contamination that may occur from accidents, cargo shifts, package failures, loading, unloading, and handling problems is limited in scale and impact, infrequent, and generally amenable to clean-up; is small. The changes would affect the alternate tests used to qualify special form radioactive material; however, the proposed action would not result in significant changes to the currently available tests or the number of tests performed.

The proposed action would affect the costs associated with transporting some material and the routes chosen to ship this material could change, because some material would no longer be classified as Class 7 (radioactive) material. The proposed action is not expected to significantly change the quantity or volume of radioactive material transported. Many of the

environmental impacts associated with these amendments coincide with impacts arising from the companion DOT rulemaking and will not significantly change the impacts from previous transportation and packaging rulemakings.

IV. ALTERNATIVES TO THE PROPOSED ACTION

The following alternatives were considered.

Alternative 1: The No-Action Alternative

Under this alternative, the NRC would take no action. This would leave in place the current regulations. The environmental impacts associated with this alternative have been evaluated, as described in Section III. The environmental impacts of the changes are small when considering routine conditions of transportation and the effects of transportation accidents.

This alternative does not include changes to the low-level material exemption. Material that, if the changes were made, would qualify for the low-level material exemption would instead continue to be transported as Class 7 (radioactive) material. This may cause the material to be transported over longer routes to avoid fees or other restrictions, which would involve small impacts. Because the requirements that apply to this material do not significantly affect the radiological exposures, the radiological impacts would be small. The impacts from not making the change to include non-radioactive solid objects with radioactive substances present on any surfaces in quantities that do not exceed the level in the definition of contamination would be similar to the impacts if the change were made and would be small.

This alternative does not include adding additional restrictions to the fissile material exemption for uranium enriched in uranium-235 to a maximum of one percent by weight, which, if made, would reduce the small likelihood of the material becoming critical during transport and the possible environmental contamination that could result.

This alternative would not adopt more up to date tests. Because the tests in ISO 2919:1980(E) and ISO/TR4826:1979(E) are not recognized as being incorporated by reference, tests in these consensus standards could not be used by NRC licensees without an exemption. There could be small negative impacts from not making this change, because the tests specified in TS-R-1, which are currently included in 10 CFR Part 71, are less stringent than the tests in the consensus standards.

If the NRC and the DOT do not make changes that maintain consistency between their regulations, there could be increased regulatory uncertainty as licensees would need to determine what is actually allowed and resolve inconsistencies between the NRC and DOT requirements. This may result in additional costs for domestic transportation of radioactive material. If changes are not made to increase the compatibility with the international transportation standards, international transportation of radioactive material could be more difficult and costly for some materials. Licensees would need to meet both agencies' requirements which could add to the cost and may place the licensee at a competitive disadvantage.

The NRC rejected this alternative, because it would not correct inconsistencies with the IAEA's international transportation standards, would allow inconsistencies to develop between the NRC's regulations and DOT's regulations that apply to the packaging and transportation of radioactive material, and would not make necessary changes to make 10 CFR Part 71 more consistent and compatible with the IAEA's transportation standards.

Alternative 2: IAEA-DOT Compatibility

Under this alternative, the NRC would conduct a rulemaking that was limited to making the NRC's regulations compatible with the 2009 edition of the IAEA's international transportation standards (TS-R-1) and the changes to DOT's requirements. The NRC would not make any

NRC-initiated, substantive changes. The environmental impacts associated with this alternative have been evaluated, as described in Sections III.A, III.B, III.D, and III.E. The environmental impacts of the changes are small when considering routine conditions of transportation and the effects of transportation accidents. The primary effects from this alternative will be in the form of radiological exposure; however, the changes are small and generally address quantities of materials that pose little risk during either routine conditions of transportation or in cases of accidents. The change in risk is small for potential contamination resulting from accidents, cargo shifts, package failures, loading, unloading, and handling problems is limited in scale and impact, infrequent, and generally amenable to clean up.

The impacts would be the same as those for the proposed action with the following exceptions. This alternative does not include adding additional restrictions to the fissile material exemption for uranium enriched in Uranium-235 to a maximum of one percent by weight, which, if made, would reduce the small likelihood of the material becoming critical during transport and the possible environmental contamination that could result.

This alternative would not result in significant changes to currently available tests or the number of tests performed. Many of the environmental impacts associated with these amendments coincide with impacts arising from the companion DOT rulemaking and do not significantly change the impacts from previous transportation and packaging rulemakings. Consequently, the proposed amendments will not involve any significant environmental impacts, including consideration of direct, indirect, and cumulative impacts.

The NRC rejected this alternative, because it would not make additional needed changes to 10 CFR Part 71. For example, this alternative would not change the fissile exemption criteria.

V. ALTERNATIVE USE OF RESOURCES

There are no irreversible commitments of resources determined in this assessment.

VI. AGENCIES AND PERSONS CONTACTED

The NRC consulted with the DOT during the preparation of the final rule and the preparation of this Environmental Assessment, consistent with the memorandum of understanding between the NRC and the DOT (44 FR 38690; July 2, 1979). The NRC requested the views of the Agreement States on the Environmental Assessment for this rule. The NRC did not receive any comments from the Agreement States.

VII. FINDING OF NO SIGNIFICANT IMPACT

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, that the amendments are not a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The amendments would change the requirements for packaging and transportation of radioactive material. The amendments would make changes to harmonize the NRC's regulations with the 2009 edition of the IAEA's transport regulations (TS-R-1) and the DOT's regulations for the transportation of radioactive material; expand the exemption for the domestic shipping of natural materials and ores containing naturally occurring radionuclides; reduce the scope of the 10 CFR 71.15(d) exemption; and make changes to the regulations that apply to quality assurance programs. The environmental impacts arising from the changes have been evaluated and would not involve any significant environmental impact. This includes

consideration of direct, indirect, and cumulative impacts. The amendments are procedural in nature and of themselves would have no significant impact on the environment.

The determination of this Environmental Assessment is that there will be no significant impact to the public from this action.