

RULEMAKING ISSUE NOTATION VOTE

December 13, 2012

SECY-12-0166

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

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

PURPOSE:

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

SUMMARY:

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

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

BACKGROUND:

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

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

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

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

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

DISCUSSION:

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

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

Exemption of Low-Level Materials

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

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

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

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

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

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

Fissile Material Exemption

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

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

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

Quality Assurance

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

General License Changes

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

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

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

AGREEMENT STATE ISSUES:

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

The staff has analyzed the proposed rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, [A](#)Categorization Process for NRC Program Elements.[C](#) The proposed changes include program elements that are classified as Compatibility Category "NRC" and program elements that are a matter of compatibility with the Agreement States and are assigned Compatibility Categories "B," "C," and "D."

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

COMMITMENTS:

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

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

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

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

RECOMMENDATIONS:

That the Commission:

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

Note:

- a. That the proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
- b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
- c. That a draft Regulatory Analysis has been prepared for this rulemaking ([Enclosure 2](#)).
- d. That a draft Environmental Assessment has been prepared for this rulemaking ([Enclosure 3](#)).
- e. That appropriate Congressional committees will be informed of this action.

- f. That a press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.
- g. That Office of Management and Budget (OMB) review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

RESOURCES:

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

SCHEDULE:

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

COORDINATION:

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

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-A111

[NRC-2008-0198]

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission), in consultation with the U.S. Department of Transportation (DOT), is proposing to amend its regulations for the packaging and transportation of radioactive material. These amendments would make NRC regulations conform to revisions to the International Atomic Energy Agency (IAEA) regulations for the international transportation of radioactive material and maintain consistency with DOT regulations. These changes are necessary to maintain a consistent regulatory framework for the transportation and packaging of radioactive material. These changes would make the regulation of quality assurance programs more efficient by (1) allowing changes that do not change quality assurance approval holder commitments to be made without prior NRC approval and (2) extending the duration of quality assurance program approvals. These changes would clarify the responsibilities of general licensees and further limit the

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

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

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

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0198. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

You may submit comments on the information collections by the methods described in the **SUPPLEMENTARY INFORMATION** section of this document, under the heading, “Paperwork Reduction Act Statement.”

For additional direction on accessing information and submitting comments, see “Accessing Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Firth, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-6628; e-mail: James.Firth@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Accessing Information and Submitting Comments
- II. Background
- III. Discussion
 - A. What Action is the NRC Taking?
 - B. Who is Affected by this Action?
 - C. Which Changes are Being Made to Increase the Compatibility with the International Atomic Energy Agency Regulations (TS-R-1) and Consistency with the DOT Regulations?
 - D. How is the NRC Changing the Exemption for Materials with Low Activity Levels?
 - E. How is the Qualification of Special Form Radioactive Material Changing?
 - F. What Changes are Being Made to Appendix A, “Determination of A₁ and A₂ Values,” to 10 CFR Part 71?
 - G. How Would the Responsibilities of Certificate Holders and Licensees Change with these Amendments?

- H. Why is Renewal of My Quality Assurance Program Description not Necessary?
- I. What Changes Can be Made to a Quality Assurance Program Description without Seeking Prior NRC Approval?
- J. How Frequently do I Submit Periodic Updates on My Quality Assurance Program Description to the NRC?
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- L. What Changes are Being Made to General Licenses?
- M. How is the Exemption from Classification as Fissile Material (10 CFR 71.15) Changing?
- N. What Other Changes is the NRC Making to its Regulations for the Packaging and Transportation of Radioactive Material?
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- P. What should I Consider as I Prepare My Comments to the NRC?
- IV. Section-by-Section Analysis
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- VII. Availability of Documents
- VIII. Plain Writing
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- X. Finding of No Significant Environmental Impact
- XI. Paperwork Reduction Act Statement
- XII. Public Protection Notification
- XIII. Regulatory Analysis

XIV. Regulatory Flexibility Certification

XV. Backfitting and Issue Finality

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2008-0198 when contacting the NRC about the availability of information for this proposed rule. You may access information related to this proposed rulemaking, which the NRC possesses and is publicly-available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0198.
- **NRC Agencywide Documents Access and Management System (ADAMS):** You may access 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. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the section of this notice entitled, *Availability of Documents*.
- **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.

B. Submitting Comments

Please include Docket ID NRC-2008-0198 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submissions. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

Background

The NRC is revising its regulations for the safe transportation of radioactive material to make them compatible with those of the IAEA. The revised rule, in combination with a corresponding amendment of Title 49 of the *Code of Federal Regulations* (49 CFR), by the DOT (76 FR 50332; August 12, 2011), would 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). The NRC is also making revisions to maintain consistency with revisions to DOT

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

Compatibility with IAEA and Consistency with DOT Transportation Regulations

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

On January 26, 2004 (69 FR 3698), the NRC published in the *Federal Register* a final revision to 10 CFR part 71, “Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments.” That revision, in combination with a parallel revision of the DOT hazardous materials transportation regulations, brought the United States domestic transport regulations into general accord with the 1996 edition of TS-R-1 (as amended

in 2000). The DOT published its corresponding revision to Title 49 parts 171 - 178 on the same date (69 FR 3632; January 26, 2004).

The IAEA periodically reviews and revises the IAEA international transportation standards to reflect knowledge gained in scientific and technical advances and accumulated experience. In 2002, the IAEA began using a 2-year review cycle. In each review cycle, the IAEA will invite Member States — the U.S. is a Member State and the DOT is the U.S. competent authority before the IAEA for radioactive material transportation matters — to submit for consideration issues or problems that could result in changes to the IAEA transportation regulations and the associated guidance. These issues and problems are then considered by the IAEA Transportation Safety Standards Committee (TRANSSC) and, if approved by TRANSSC, will be developed into specific proposed changes to the transportation regulations. The specific proposed changes are then considered at a second TRANSSC meeting. The IAEA will then issue those approved changes at the second TRANSSC meeting for formal review and comment by Member States.

The IAEA has invited Member States to submit comments and suggest changes to the regulations as part of these periodic revisions. The NRC and DOT have sought public input related to the proposed revisions. On July 22, 2003, the DOT held a public meeting, with the NRC participating, to obtain public views on proposed changes to the 1996 Edition of TS-R-1 and accepted written comments through August 8, 2003. On November 5, 2003, the DOT held a public meeting, with the NRC participating, seeking public views on the DOT positions on the proposed changes to TS-R-1. The NRC published *Federal Register* notices on June 26, 2003 (68 FR 37986); October 24, 2003 (68 FR 60886); April 23, 2004 (69 FR 21978); April 27, 2005 (70 FR 21684); and November 21, 2007 (72 FR 65470), soliciting public input on proposed revisions to TS-R-1. Subsequent to the 1996 edition of TS-R-1 (as amended in 2000), the IAEA published revisions to TS-R-1 in 2003, 2005, and 2009.

This rulemaking effort involves harmonizing the NRC regulations at 10 CFR part 71 with changes to the IAEA transportation regulations through “Regulation for the Safe Transport of Radioactive Material, 2009 Edition,” No. TS-R-1. Copies of TS-R-1 may be obtained from the United States distributors, Bernan, 15200 NBN Way, P.O. Box 191, Blue Ridge Summit, PA 17214; telephone: 1-800-865-3457; e-mail: customer care@bernan.com, or Renouf Publishing Company Ltd., 812 Proctor Ave., Ogdensburg, NY 13669-2205; telephone: 1-888-551-7470; e-mail: orders@renoufbooks.com. An electronic copy may be found at the following IAEA Web site: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1384_web.pdf. The regulations in TS-R-1 represent an accepted set of requirements that are considered to provide a high level of safety in the packaging and transportation of radioactive materials and provide a basis and framework that facilitates the development of internationally-consistent regulations. Internationally-consistent regulations for the transportation and packaging of radioactive material reduce impediments to trade; facilitate international cooperation; and, when the regulations provide a high level of safety, can reduce risks associated with the import and export of radioactive material. Harmonization represents the effort to increase the consistency or compatibility between national regulations and the internationally-accepted requirements, within the constraints of an existing national legal and regulatory framework.

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

Historically, the NRC has coordinated its revisions to 10 CFR part 71 with the DOT, because the DOT is the U.S. competent authority for transportation of hazardous materials. “Radioactive Materials” is a subset of “Hazardous Materials” in Title 49 regulations under DOT authority. The DOT hazardous materials regulations are found in parts 171 -177 of 49 CFR.

Currently, 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 described in a memorandum of understanding (MOU) (44 FR 38690; July 2, 1979). Consistent with this MOU, the NRC is continuing to coordinate its efforts with the DOT in this rulemaking process. Refer to the DOT corresponding rule for additional background on the proposed changes in this notice.

Scope of 10 CFR Part 71 Rulemaking

The NRC staff evaluated recent changes in the IAEA's transportation standards through the 2009 edition of TS-R-1 to identify changes to be made in 10 CFR part 71. Based on this effort, the NRC staff identified a number of areas in 10 CFR part 71 that need to be addressed in this rulemaking process as a result of the changes to the IAEA regulations. These changes are discussed in Section III of this document, question C, "Which Changes are Being Made to Increase the Compatibility with the International Atomic Energy Agency Regulations (TS-R-1) and Consistency with DOT Regulations?"

The NRC is also proposing a number of self-initiated changes to its regulations that are not related to either compatibility with IAEA regulations or consistency with DOT regulations. These NRC changes would affect administrative procedures for the quality assurance program requirements described in 10 CFR part 71, subpart H, re-establish restrictions on material that qualifies for the fissile material exemption, clarify the requirements for a general license, clarify the responsibilities of certificate holders and licensees when making preliminary determinations, and make other editorial changes.

Fissile Material Exemption

In 1997, the NRC issued an emergency final rule (62 FR 5907; February 10, 1997) that revised the regulations on fissile material exemptions and the general licenses that apply to fissile material. The NRC determined that good cause existed under Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)), to publish this final rule without notice and opportunity for public comment. Further, the NRC also determined that good cause existed, under Section 553(d)(3) of the APA (5 U.S.C. 553(d)(3)), to make the final rule immediately effective. Notwithstanding the final status of the rule, the NRC provided for a 30-day public comment period. The NRC subsequently published in the *Federal Register* (64 FR 57769; October 27, 1999) a response to the comments received on the emergency final rule and a request for information on any unintended economic impacts caused by the final rule. Based on the public comments on the emergency final rule, the NRC staff contracted with 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 regulations may be excessive for shipments where water moderation is the only concern. The ORNL study recommended that the NRC revise 10 CFR part 71. The ORNL made a recommendation that 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

¹ NUREG/CR-5342, "Assessment and Recommendations for Fissile-Material Packaging Exemptions and General Licenses within 10 CFR Part 71," July 1998.

mass of U-235, hereafter referred to as uranium enriched to a maximum of 1 percent. Specifically, ORNL recommended (1) that a definition of “homogeneity” be developed that could be clearly understood for use with uranium enriched to a maximum of 1 percent, (2) the term “lattice arrangement” be clarified or not used, and (3) if the definitions for homogeneity and lattice arrangement cannot be provided, a restriction on beryllium (Be), deuterium oxide (e.g., D₂O or heavy water), and carbon (graphite) (C) should be maintained. The ORNL recommended that the moderator criteria restricting the mass of Be, C, or D₂O 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 staff indicated that it agreed with the ORNL recommendations (67 FR 21390; April 30, 2002) and removed the homogeneity and lattice prevention requirements from the fissile material exemptions.

The ORNL recommendations were considered when the NRC proposed changes to 10 CFR part 71 (67 FR 21390; April 30, 2002) to make NRC regulations more consistent and compatible with IAEA regulations and to make changes to the fissile material exemption requirements to address the unintended economic impact of the NRC emergency final rule entitled “Fissile Material Shipments and Exemptions” (62 FR 5907; February 10, 1997). In its final rule (69 FR 3698; January 26, 2004) to make 10 CFR part 71 compatible with the IAEA regulations and make other transportation safety amendments, the NRC removed the restriction that, to qualify for the fissile material exemption, uranium enriched in U-235 is distributed homogeneously throughout the package and does not form a lattice arrangement within the package, and redesignated the section for fissile material exemptions from § 71.53 to § 71.15. Based on a comment that shippers would have difficulty implementing the proposed rule language, the NRC determined that it would be impractical to implement a restriction based on the proposed ratio of the restricted moderators to the fissile mass and changed the restriction to

require that the mass of beryllium, graphite, and hydrogenous material enriched in deuterium be less than 5 percent of the mass of uranium; the NRC concluded that limiting the mass of these moderators to less than 5 percent of the uranium mass would assure subcriticality for all moderators of concern.

Subsequent to the 2004 rulemaking, the U.S. Department of Energy (DOE) was planning a shipment of large quantities of low-enriched fissile material that would qualify for the exemption at 10 CFR 71.15(d). Analyses performed by the DOE indicated that large arrays of heterogeneous uranium with enrichment of one percent by weight of U-235 could exceed a k_{eff} of 0.95 when optimally moderated by water. For the material to become critical,² the k_{eff} would need to be greater than or equal to 1.0. However, the quantity and geometric arrangement of this material exceeded a k_{eff} of 0.95, which is typically used as a limit in regulatory assessments of package designs for the transport of fissile material. The sensitivity of k_{eff} to increases in the quantity of fissile material and changes in geometry will depend on the properties of the material. For uranium enriched to a maximum of one percent and k_{eff} greater than 0.95, k_{eff} is very insensitive to changes in geometry and quantity; consequently, significantly larger quantities of material would be required to get k_{eff} close to 1.0.

Quality Assurance Program Approvals

Part 71 of 10 CFR does not include provisions for making changes to an approved quality assurance program without obtaining prior NRC approval before implementing the change. The requirement to obtain prior NRC approval currently applies to all changes, no matter how insignificant in importance they are to safety. Consequently, the process can be

² For transportation purposes, nuclear criticality means a condition in which an uncontrolled, self-sustaining and neutron-multiplying fission chain reaction occurs. Nuclear criticality is generally a concern when sufficient concentrations and masses of fissile material and neutron moderating material exist together in a favorable configuration. The neutron moderating material cannot achieve criticality by itself in any concentration or configuration. It can enhance the ability of fissile material to achieve criticality by slowing down neutrons or reflecting neutrons.

overly burdensome and inefficient for both the licensee and the NRC. For example, a change in the quality assurance program to correct typographical errors or punctuation would need to be submitted and approved by the NRC.

In the past, the NRC observed several instances in which holders of a 10 CFR part 71 quality assurance program approval had made changes to their NRC-approved quality assurance program before obtaining NRC approval. Although many of the changes were found acceptable by the NRC after they were reviewed, some of the changes did not satisfy the respective requirements of 10 CFR part 71, subpart H. In Information Notice 2002-35 (December 20, 2002; ADAMS Accession No. ML023520339), the NRC indicated that it was considering changes to 10 CFR part 71 to provide a method similar to 10 CFR 50.54(a)(3) and (4) for making changes to 10 CFR part 71 quality assurance programs.

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. This change was announced in “NRC Regulatory Information Summary (RIS) 2004-18, Expiration Date for 10 CFR Part 71 Quality Assurance Program Approvals” (December 1, 2004; ADAMS Accession No. ML042160293). After making this change, the NRC evaluated whether a change should be made in the regulations to codify the effective term of the quality assurance program approval or whether any expiration date for the quality assurance program approval was necessary.

I. Discussion

A. What Action is the NRC Taking?

The NRC is proposing to amend its regulations to make them more consistent or compatible with the IAEA international transportation regulations. These changes are in response to changes introduced in the 1996 (as amended in 2003), 2005, and 2009 editions of TS-R-1. The NRC is proposing to revise its regulations to be consistent with DOT hazardous materials regulations to maintain a consistent framework for the transportation and packaging of radioactive material.

The NRC is proposing to make changes that would clarify the requirements to obtain a general license and the responsibilities of general licensees. The NRC is proposing to make changes that would clarify the roles of users of NRC-approved packaging and certificate holders or applicants for a certificate of compliance (CoC). Also, the NRC is proposing to make changes that would make the regulation of quality assurance programs more efficient. The NRC is proposing to issue quality assurance program approvals that would not expire, removing the need for the approval to be renewed, and would revise the current quality assurance program approvals so that they would not expire. The NRC is also proposing to allow those changes that do not reduce the commitments in an approved quality assurance program to be made without prior NRC approval.

The NRC is proposing to make changes that would change the responsibilities of licensees and certificate holders for making the preliminary determinations in § 71.85.

Other proposed changes would correct errors and clarify the regulations.

B. Who is Affected by this Action?

This action would affect NRC licensees authorized by a specific or general license issued by the Commission to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, or transports the material outside of the site of usage as specified in the NRC license, or transports that material on public highways; holders of, and applicants for, a CoC; and holders of a quality assurance program approval. This action would change requirements that are matters of compatibility. Agreement States would be required to update their regulations and Agreement State licensees would be affected by the changes to the Agreement State regulations.

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

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

1. In the 2003 Edition of TS-R-1, the IAEA changed the scope of TS-R-1 as it applies to natural materials and ores by adding language that addresses the processing of these materials (paragraph 107(e) of the 2009 edition of TS-R-1). The NRC is proposing to include the concept of processing into the provisions that apply to natural materials and ores in the exemptions for low-level materials at § 71.14.

2. The NRC is proposing to adopt 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 proposed change, a definition of “contamination” corresponding to the definition in TS-R-1 would be added to § 71.4.

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

4. The NRC is proposing to adopt the use of the Class 5 impact test prescribed in the International Organization for Standardization (ISO) document 2919, “Radiation protection – Sealed radioactive sources – General requirements and classification,” Second Edition (February 15, 1999), ISO 2919:1999(E), for special form radioactive material, provided the mass was less than 500 grams.

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

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

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

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

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

9. The NRC is proposing to include krypton-79 (Kr-79) in Table A-1 and Table A-2. The A_1 and A_2 values in Table A-1 and the activity concentration for exempt material and the activity limit for exempt consignment would be consistent with the IAEA values in the 2009 edition of TS-R-1.

10. The NRC is proposing to revise footnote a to Table A-1, " A_1 and A_2 values for radionuclides" 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 in footnote a to Table 2, "Basic radionuclide values," in TS-R-1 (2009 edition), with the exception of argon-42 (Ar-42) and tellurium-118 (Te-118), which appear in footnote a to Table 2 in TS-R-1 (2009 edition), but do not appear within Table 2.

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

12. The NRC is proposing to revise the activity limit for exempt consignment for tellurium-121m (Te-121m) to be consistent with the new IAEA value.

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

14. The NRC is proposing to revise the descriptive phrases for different categories of unknown radionuclides and mixtures in Table A-3 to be consistent with the IAEA descriptions. The descriptive phrases for “Only alpha emitting nuclides are known to be present” and “No relevant data are available” would be revised.

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

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

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

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

The NRC has established an exemption at 10 CFR 71.14 that exempts licensees from the requirements of 10 CFR part 71 for certain natural materials and ores. The exemption for low-level materials exempts licensees from the requirements of 10 CFR part 71 with respect to the shipment or carriage of material that qualifies for the exemption and they would be allowed

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

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

Natural material and ore containing naturally occurring radionuclides that are not intended to be processed for these radionuclides could qualify for the low-level material exemption at 10 CFR 71.14(a)(1). With the correction to the definition of LSA-I material, uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides which are intended to be processed for these radionuclides may be able to qualify for the low-level material exemption at § 71.14(b)(3), provided that the other restrictions are satisfied. The restrictions include: 1) the package 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 regulations in 49 CFR parts 107, 171 through 180, and 390 through 397. If the DOT regulations are not applicable to a shipment of licensed material, § 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 regulations. Section 71.88 would 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 would not be able to 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 of natural material or ore that has been processed and that may still qualify for the exemption, provided that the processed material has not been incorporated into a manufactured product.

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

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

The NRC is proposing to update the alternate tests in § 71.75 that may be used for the qualification of special form radioactive material to tests in more recent editions of the consensus standards. The NRC is proposing to incorporate 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 proposing to incorporate by reference the leaktightness tests specified in ISO document 9978:1992(E). The IAEA has adopted, 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 Class 4 impact test in ISO 2919:1999(E) would replace the impact test in § 71.75(d) — the Class 4 impact test in ISO 2919, “Sealed Radioactive Sources — Classification,” first edition (1980) — and would 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, would 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) would replace the temperature test in § 71.75(d) — the Class 6 temperature test in ISO 2919, “Sealed Radioactive Sources — Classification,” first edition (1980). 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 would continue to be more stringent than the testing required by § 71.75(b).

The leaktightness tests prescribed in ISO 9978:1992(E) would replace the tests in ISO/TR 4826, “Sealed Radioactive Sources — Leak Test Methods,” (1979). 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 proposing to revise the definition of special form radioactive material 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 would allow material tested using requirements in effect at the time of the testing to continue to be used. The NRC is proposing to correct the reference to the version of § 71.4 in the CFR that was in effect on March 31, 1996, by changing the date of the revision from January 1, 1983, to January 1, 1996.

The NRC is proposing to replace “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 is intended to clarify the description of the billet and to maintain consistency with the language used by the DOT in 49 CFR 173.469.

F. What Changes are Being Made to Appendix A, “Determination of A_1 and A_2 Values,” to 10 CFR Part 71?

The NRC is proposing the following changes to appendix A.

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

The NRC is proposing to specifically address 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. By including this equation, the NRC would increase the consistency between 10 CFR part 71 and TS-R-1 and would provide additional clarity on how to address cases where a package will

contain both special form and normal form material. The equation is similar to those already used in 10 CFR part 71 for mixtures of special form material and mixtures of normal form material.

2. Table A-1, “ A_1 and A_2 Values for Radionuclides.”

The NRC is proposing to revise Table A-1 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 NRC is proposing to add an entry for Kr-79, which has been added to Table 2 in the 2009 edition of TS-R-1; adopt the A_1 and A_2 values for Cf-252; revise 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 move and revise footnote c, which applies to Ir-192, so that the footnote applies only to Ir-192 in special form material.

The A_1 and A_2 values are used for determining what 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 “other than special form” material allowed in a Type A package. 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 IAEA has added an entry for Kr-79 in the Table 2 of the 2009 edition of TS-R-1. The NRC is proposing to adopt these radionuclide-specific values for Kr-79 in Table A-1. The radionuclide-specific values would replace the generic values in Table A-3, which are currently 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 would replace.

The IAEA has revised the A_1 value for Cf-252 to the value that currently applies to domestic transportation. In the 2004 final rule for 10 CFR part 71 (69 FR 3698; January 26, 2004), the NRC did not adopt the A_1 value for Cf-252 in TS-R-1 for domestic transportation, because the NRC was aware that the IAEA was considering changing the value back to the value that has been in 10 CFR part 71; the IAEA has subsequently made this change. The NRC is proposing to adopt the A_1 value for Cf-252, which would apply to both international and domestic transportation, and to adopt the IAEA value for A_2 . The NRC is proposing to delete the A_2 value that applies only to domestic transportation. Making this change would improve the harmonization of 10 CFR part 71 with TS-R-1 by adopting the A_2 value for Cf-252 in TS-R-1. Because the A_2 value for Cf-252 was established by the IAEA using the Q-system and current data for Cf-252, the A_2 value for Cf-252 would be consistent with the other values derived using the Q-system that have been incorporated into 10 CFR part 71.

The NRC is proposing to revise footnote a to Table A-1 to identify the A_1 and A_2 values that include contributions from daughter radionuclides that have a half-life that is less than 10 days. The proposed 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). Ar-42 and Te-118 would not be included, because they do not appear within Table A-1.

The NRC is proposing to revise footnote c to Table A-1 to make clear that the activity of Ir-192 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 is appropriate for Ir-192 in special form.

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

The NRC is proposing to revise Table A-2 to make the values in 10 CFR part 71 consistent with the values in TS-R-1 and to add an entry for Kr-79, which has been added to Table 2, "Basic radionuclide values," in the 2009 edition of TS-R-1. The NRC is also proposing

to update 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 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 NRC is proposing to update the activity limit for exempt consignment for Te-121m to match the values in TS-R-1.

Material that has an activity concentration that is less than the activity concentration for exempt material would pose a very low radiological risk. The activity limit for exempt consignment has been established for the transportation of material in quantities small enough for which the total activity is unlikely to result in any significant radiological exposure. This would be the case even for material that exceeds the activity concentration for exempt material.

Krypton-79 is not listed in Table A-2 and the values from Table A-3, "General Values for A_1 and A_2 ," in appendix A are 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 included in the 2009 edition of TS-R-1.

In the 2005 edition of 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. Also, to conform to International Commission on Radiological Assistance (ICRP) and IAEA changes, the activity limit for exempt consignment for Te-121m in Table A-2 is being changed from 1×10^5 Bq (2.7×10^{-6} Ci) to 1×10^6 Bq (2.7×10^{-5} Ci).

The IAEA has revised the list of parent radionuclides and their progeny included in secular equilibrium in footnote (b) to Table 2, "Basic radionuclide values" 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 removing the decay chain 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 would be 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" (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 current descriptive phrases are: 1) "only beta or gamma emitting radionuclides are known to be present," 2) "only alpha emitting nuclides are known to be present," and 3) "no relevant data are available." The NRC is proposing to adopt the descriptive phrases as revised by the IAEA in TS-R-1 in Table A-3.

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, would be used. Consequently, an A_1 value of 1 TBq (2.7 Ci) and an A_2 value of 9×10^{-5} TBq (2.4×10^{-3} Ci) would be 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.

The NRC is proposing to make several corrections to the formulas and the descriptions of the formulas that address mixtures of radionuclides in Section IV. These changes involve formatting and typographical changes in the formulas and their descriptions.

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

In the 1950s, the Atomic Energy Commission (AEC) issued package approvals to AEC licensees as amendments to their licenses and the DOT issued package approvals to non-AEC licensees. On March 22, 1973 (38 FR 8466), the AEC and the DOT entered into an MOU where the DOT agreed to adopt a requirement for AEC approval of designs of packages for the shipment of fissile material and other radioactive material exceeding Type A limits, with the exception of LSA material, and the AEC agreed to develop safety standards for the design and performance of packages and to impose these standards on AEC licensees and license-exempt contractors. Under the MOU, the AEC would issue an AEC license, an AEC CoC, or other AEC package approval directly to the person requesting the evaluation. Although the AEC, and

subsequently the NRC, certified that the packages met the regulations, they did not have regulatory authority over the certificate holders under DOT jurisdiction. On July 2, 1979 (44 FR 38690), this MOU was superseded by an MOU between the DOT and the NRC. In this MOU, it was agreed that the NRC, in consultation with the DOT, would develop safety standards for the design and performance of the packages. As the NRC developed its safety standards for the packages, it gained regulatory authority over the certificate holders.

The requirements for making the preliminary determinations have remained largely unchanged since the 1979 MOU. In discussing the routine and preliminary determinations (48 FR 35600; August 5, 1983), the Commission indicated that the user of a package always had the regulatory responsibility for preliminary and routine determinations and recordkeeping, even though the user may not own the package. The Commission also indicated that although the user could contract with some other person, perhaps the owner, to satisfy those requirements for the user, the user's records must demonstrate that the requirements have been satisfied. Although leaktightness tests related to the package design are required as a condition of the package design approval, the Commission has indicated that it considers that in the case of radioactive material packages, integrity of the containment (including closures, valves, and other routes of escape) should be demonstrated for each fabricated package before first use.

The NRC experience is that licensees have never made preliminary determinations themselves, unless they also happen to be certificate holders. Based on the NRC extensive experience inspecting the activities of certificate holders and NRC licensees who use packages, the NRC is not aware of any NRC licensee that performs preliminary determinations unless they are also the certificate holder for the package design. The scope of user-only quality assurance program approvals, which are issued to licensees who are not also holders of a CoC, do not include the testing required to make the preliminary determinations. Licensees lease or buy these packages from the certificate holder, or fabricator, and most packages are already

marked by the certificate holder. The NRC has identified cases where the durable marking of the packaging required by § 71.85 was done incorrectly by a certificate holder. Because the licensee is responsible for the preliminary determinations, enforcement could not be taken against the certificate holder for improperly marking the packaging.

The Commission is proposing to make changes to § 71.85 that would make certificate holders, not licensees, responsible for making the preliminary determinations before the first use of each package. The preliminary determinations involve evaluating, testing, and marking the packaging. The DOT requirements at 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. The Commission is proposing to require the licensee to ascertain that the preliminary determinations involving evaluating, testing, and marking the packaging have been made. The licensee would still make the required routine determinations at § 71.87. As required by § 71.91(d), both licensees and certificate holders would still be required to maintain sufficient written records to furnish evidence of the quality of the packaging, which includes the results of the determinations required by § 71.85.

The Commission is proposing to make these changes, because it is more appropriate to assign the responsibility to certificate holders for marking the packaging. Only certificate holders are authorized to design and fabricate packagings and only certificate holders would have a full scope quality assurance program approval, which would allow them to perform the testing required as part of the preliminary determinations under an approved quality assurance program. However, licensees would need to retain their responsibility to determine that the packaging has been manufactured, assembled, and marked appropriately and that the packaging does not have any defects that could significantly reduce the effectiveness of the packaging. By assigning the responsibility for making the determinations to the certificate

holder, the NRC would be able to streamline the implementation of its regulations and have the regulations better reflect current practice.

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 to provide an opportunity for the NRC staff to periodically review the quality assurance programs and for the NRC to maintain periodic contact with the quality assurance program approval holders. The limited duration of the approval facilitated the NRC recordkeeping relating to points of contact, package fabrication, use activities, and other administrative activities.

In 2004, the NRC extended the duration of its quality assurance program approvals from 5 years to 10 years, because the NRC had determined that the periodic contact associated with the 5-year renewal period was less important than it was previously and the duration of the approval could be lengthened. The NRC announced this change in RIS 2004-18, "Expiration Date for 10 CFR Part 71 Quality Assurance Program Approvals" (December 1, 2004).

The NRC is changing its practice regarding the duration of its quality assurance program approvals. The NRC would no longer limit the duration of its quality assurance program approvals issued under 10 CFR part 71. The NRC is proposing changes to 10 CFR part 71 to implement this change and to enhance the periodic communication between the NRC and the quality assurance program approval holders. The NRC would reissue its quality assurance program approval for Radioactive Material Packages (NRC Form 311) without an expiration date. As discussed in Section III, question I, "What Changes Can be Made to a Quality Assurance Program Description without Seeking Prior NRC Approval?," and question J, "How Frequently do I Submit Periodic Updates on My Quality Assurance Program Description to the

NRC?,” the NRC is proposing to require quality assurance program approval holders to periodically report changes in their quality assurance program description to the NRC. 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 not necessary to provide the NRC with assurance that the quality assurance program approval holders would continue to be able to adequately maintain and implement their approved quality assurance program.

As discussed under question I, “What Changes Can be Made to a Quality Assurance Program Description without Seeking Prior NRC Approval?,” the NRC would continue to approve quality assurance program description changes that reduce commitments made to the NRC in quality assurance program descriptions that have been approved by the NRC. Every 24 months, each quality assurance program approval holder would be required to report those changes that do not reduce commitments made to the NRC in a quality assurance program description approved by the NRC. Holders of a CoC and applicants for a CoC are subject to periodic inspection of their quality assurance program (approximately every 3 years) by the NRC. Licensees who use packages are inspected on an as-needed basis.

As discussed under question P, “What Should I Consider as I Prepare My Comments to the NRC?,” the NRC is specifically requesting comment on the proposed approach to reporting changes to approved quality assurance program descriptions.

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

Currently, quality assurance program descriptions approved under 10 CFR part 71 cannot be changed without NRC approval. Therefore, all changes to 10 CFR part 71 quality assurance programs, irrespective of their significance or importance to safety, must 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, consistent with the requirements at § 50.54. The NRC is proposing to allow some changes to be made to quality assurance programs approved under 10 CFR part 71 without obtaining NRC approval. The process for making changes to approved quality assurance program descriptions would 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 would result in a more consistent approach to allowing changes to approved quality assurance programs. The NRC is proposing to establish a process that would require NRC approval to be obtained for those changes that are most important to safety, but would allow other changes to be implemented without obtaining NRC approval.

Quality assurance program approval holders would be required to obtain NRC approval before making any change to their quality assurance program description that would reduce the commitments that they have made to the NRC. Quality assurance program approval holders would not be required to submit changes to their quality assurance program descriptions, if those changes do not reduce the commitments that they have made to the NRC. 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 would not require NRC approval. Changes to reporting responsibilities; functional responsibilities; functional relationships; and some editorial or punctuation changes may be substantive and have the potential to reduce commitments made to the NRC and, in these instances, would require prior NRC approval before being implemented. The following includes types of changes that the NRC would not consider as reducing a commitment made to the NRC:

1. The use of a quality assurance standard approved by the NRC, which is more recent than the quality assurance standard in the current quality assurance program at the time of the change;
2. The use of generic organizational position titles that clearly denote the function of the position, supplemented as necessary by descriptive text, rather than specific titles, provided that there are no substantive changes 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;
4. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the holder of the quality assurance program approval has committed 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.

Quality assurance program approval holders would also need 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?

The NRC would continue to require quality assurance program approval holders to obtain NRC approval of any change to their approved quality assurance program description that would reduce any commitment in the quality assurance program description approved by the NRC before they implement the change. The NRC would require the following information

to be provided for its review: a description of the proposed changes to the approved quality assurance program description, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the requirements of subpart H.

The NRC is proposing to require that quality assurance program approval holders would report changes to their approved quality assurance program that do not reduce any commitments in the quality assurance program description approved by the NRC every 24 months. These changes would not require NRC approval before they can be implemented. If the quality assurance program approval holder has not made any changes to their approved quality assurance program description during the preceding 24-month period, they would report to the NRC that no changes have been made.

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 before they are implemented and with the periodic reporting of the less significant changes every 24 months, the NRC would 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 discussed under question H, “Why is Renewal of My Quality Assurance Program Description not Necessary?,” the NRC would re-issue NRC Form 311 without an expiration date. The 24-month period for reporting of changes is proposed to begin on the date of the NRC approval of a quality assurance program issued with no expiration date, as specified by the date of signature at the bottom of NRC Form 311, “Quality Assurance Program Approval for Radioactive Material Packages.”

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

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

The NRC is proposing to remove the footnote in § 71.103 regarding the use of the term “licensee” in subpart H, because it is no longer necessary. The removal of the footnote does not change the quality assurance requirements in subpart H. The footnote regarding use of the term “licensee” was included to clarify that the quality assurance requirements in subpart H 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 later rulemaking to make explicit the application of those quality assurance requirements to certificate holders and applicants for a CoC. Although removing the footnote would not change the quality assurance requirements, other proposed changes to subpart H in this rulemaking would further clarify which requirements

apply to users of NRC certified packaging and which apply to applicants for, or holders of, CoCs — the entities that would be 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 proposing to change the requirements for general licenses for the following: 1) use of an NRC-approved package (§ 71.17) and 2) 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 Commission as satisfying the provisions of subpart H of 10 CFR part 71 is required to be granted the general license. The proposed changes would clarify that the licensee is responsible for maintaining copies of the appropriate documents, such as the CoC, or other approval of the package, and 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 would also clarify that making the notification in § 71.17(c)(3) to the NRC is a responsibility of the licensee, rather than a condition for obtaining the license. The proposed changes to §§ 71.17 and 71.21 would not change the current notification process and would not change the required timing or content of the notification required by § 71.17(c)(3) or any other reporting requirements relating to package use or, where required, the prior notification of shipments.

The proposed changes also include updating the reference in § 71.21(a) from 49 CFR 171.12 to 49 CFR 171.23. On May 3, 2007 (72 FR 25162), the DOT published a final rule that moved the requirements at 49 CFR 171.12 to paragraph (b)(11) at 49 CFR 171.23, “Requirements for the specific materials and packagings transported under the [International Civil Aviation Organization] ICAO Technical Instructions, [International Maritime Dangerous

Goods] IMDG Code, Transportation Canada [Transportation of Dangerous Goods] TDG Regulations, or the IAEA Regulations.”

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

The objective of the fissile material exemptions at § 71.15 is to facilitate the safe transport of low-risk (e.g., small quantities or low concentrations) of fissile material by exempting shipments of these materials from the packaging requirements and the criticality safety assessments required for fissile material transportation and to allow the shipments to take place without specific Commission approval. The lower amount of regulatory oversight is acceptable for these shipments, because the exemptions are established so as to ensure safety under all credible transportation conditions. Provided the exempt material is packaged consistent with the radioactive and hazardous properties of the material, there would not be any additional packaging or transport requirements for exempt fissile material beyond that noted in the specific exemption. However, exempt fissile material would still have fewer restrictions imposed than if it were to be shipped as fissile material. Therefore, for purposes of ensuring criticality safety, the exemptions consider that the material can be released from any 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 conditions assumed as part of the criticality safety assessment for package designs approved to transport fissile material.

The reactivity of uranium enriched in U-235 will depend 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; thus 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 at § 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.³ The minimum critical enrichment is the enrichment necessary for a system to have a neutron multiplication factor of one. Systems containing homogeneous mixtures of uranium enriched to less than the minimum critical enrichment (e.g., a homogeneous mixture of uranium enriched to a maximum one percent) will not be critical, irrespective of the mass or size of the system. The fissile material exemption at § 71.15(d) also limits the quantity of some less common moderating materials (beryllium, graphite, hydrogenous material enriched in deuterium) because the presence of these materials has the potential to reduce the minimum critical enrichment, increasing the potential for criticality with uranium of lower enrichment. Thus, homogeneous materials containing uranium enriched to no more than 1 percent by weight and subject to the noted restrictions on moderators will be inherently safe from a potential criticality, because they 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; thus, the minimum critical enrichment would be lower for an optimized heterogeneous system than for an optimized homogeneous system of the same material. In consideration of this fact, the current proposed change at § 71.15(d) is to add requirements 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 increase 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, "Advisory

³ 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).

Material for the IAEA Regulations for the Safe Transport of Radioactive Material” (TS-G-1.1), 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.

As described in Section II of this document, analyses performed by the DOE indicated that large arrays of uranium with enrichment of 1 percent by weight of U-235, which would 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 analyses were 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, would 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 exemption for low-enriched fissile material and have a k_{eff} greater than 0.95, the Commission believes that additional restrictions on low-enriched fissile material shipped under the fissile material exemption at § 71.15(d) are warranted.

When the Commission last identified a defect in its fissile exemption regulations, which allowed shipments to be made without prior Commission approval, the Commission published an emergency final rule to restrict the use of beryllium and other special moderators such as graphite and hydrogenous material enriched in deuterium. In this instance, the Commission chose to use normal notice-and-comment rulemaking procedures and that the proposed change did not need to be effective immediately. Uranium enriched to a maximum of 1 percent by weight is rarely available in quantities that would allow k_{eff} to exceed 0.95. In the case of uranium enriched to a maximum of 1 percent by weight, k_{eff} is not sensitive to changes in mass,

so a significant amount of additional mass would be required to increase the k_{eff} from 0.95 to a value very close to 1.0, even when geometry and moderator conditions are optimal with respect to criticality. In addition, k_{eff} is very sensitive to moderator conditions. If the moderator conditions are not optimal, k_{eff} is less sensitive to changes in mass. Therefore, it is very unlikely that even in the case of large quantities of uranium enriched to a maximum of 1 percent by weight that the moderator conditions would also be close to optimal with respect to criticality. The upper subcritical limit is the maximum allowed value of k_{eff} and includes a minimum margin of subcriticality. At a k_{eff} equal to 1, the system is considered critical.

As discussed in Section II of this document, the NRC removed both the requirement for uranium enriched to a maximum of 1 percent to be homogeneously distributed and the lattice prevention requirement. Although the NRC had determined that the limits on restricted moderators was sufficient to assure subcriticality for all moderators of concern, the NRC 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 proposing to reinstate 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 would be 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, should 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, should be less than 5.0 percent of the uranium mass. Although there are heterogeneity effects at very small scales, the Commission does not believe that it is necessary to require homogeneity with respect to particle size. Further, the Commission 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 regulations, which require that the fissile nuclides be essentially homogeneously distributed. Restricting the variability in concentration is not sufficient for limiting the reactivity of the uranium enriched to a maximum of 1 percent. Therefore, the Commission is also proposing to reinstate the lattice prevention criterion. The contents of the package should 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 Commission believes that this restriction is too narrow and should apply irrespective of the form of uranium. As discussed under question P, the NRC is seeking comment on the homogeneity and lattice prevention requirements for the exemption for uranium enriched to a maximum of 1 percent. The Commission is requesting comment on the clarity of the homogeneity and lattice prevention criteria for implementation.

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 has been deleted. Paragraph 71.19(a) is currently reserved. Other paragraphs in § 71.19 would be redesignated. In redesignated paragraph 71.19(b)(2), transitional language that is no longer needed would be 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.

References to § 71.20 in § 71.0 would be removed, because § 71.20 has expired and been removed from the regulations.

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

In § 71.101, the NRC is proposing to make changes that would make the requirements more precise. Paragraphs 71.101(a) and 71.101(c)(2) would be revised to clarify the responsibilities of licensees and certificate holders and applicants for a CoC. The quality assurance requirements pertaining to the design, fabrication, testing, and modification of packaging apply to certificate holders and applicants for a CoC. Licensees are responsible for the quality assurance requirements that apply to their use of the packaging for the shipment of licensed material. Paragraph 71.101(c) would be changed to remove the overlap between paragraphs (c)(1) and (c)(2), by removing the reference to licensees in paragraph (c)(2).

O. When do These Proposed Amendments Become Effective?

The NRC will coordinate the effective date for this rule with the DOT. As described under question P, “What Should I Consider as I Prepare My Comments to the NRC?,” the NRC is requesting comments on the cumulative effects of regulation (CER), including comments that would inform the amount of time that would be sufficient to implement the proposed amendments. The NRC intends that the new regulations would become effective no sooner than 90 days after the final rule is published in the *Federal Register*.

P. What Should I Consider as I Prepare My Comments to the NRC?

Tips for preparing your comments - when submitting your comments, remember to:

1. Identify the rulemaking (RIN 3150-AI11; NRC-2008-0198).
2. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
3. Describe any assumptions and provide any technical information and/or data that you used.
4. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
5. Provide specific examples to illustrate your concerns, and suggest alternatives.
6. Explain your views as clearly as possible.
7. Make sure to submit your comments by the comment period deadline identified.
8. See Section VIII for the request for comments on the use of plain writing, Section IX for the request for comments on the adoption of voluntary consensus standards, Section XI for the request on the reporting and recordkeeping burden, and Section XII for the request for comments on the draft regulatory analysis.
9. The NRC is specifically requesting comments on the following items:
 - a. As discussed under question J, "How Frequently do I Submit Periodic Updates on My Quality Assurance Program to the NRC," the NRC is proposing to require quality assurance program approval holders to submit a report every 2 years that describes the changes that were made to their quality assurance program that do not reduce a commitment in the quality assurance program description approved by the NRC. The NRC is seeking to balance the regulatory burden for submitting this information with the NRC need to ensure that the NRC has current information for its regulatory oversight of quality assurance program approval holders, which includes using the information for inspections. Inspections of certificate

holders occur approximately every 3 years and inspections of licensees who use packages occur on an as-needed basis. The NRC is requesting comment on whether a different frequency for reporting changes to an approved quality assurance program that do not reduce a commitment in a quality assurance program description approved by the NRC would be more appropriate?

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

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

- i. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs and procedures?

- ii. If current or projected CER challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what period of time would be sufficient)?
- iii. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendments requests, inspection findings of a generic nature) influence the implementation of the proposed requirements?
- iv. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences and how should they be addressed?
- v. Please comment on the NRC cost and benefit estimates in the regulatory analysis that supports the proposed rule.

IV. Section-by-Section Analysis

Section 71.0 Purpose and scope.

Paragraph (d)(1) would be revised to delete § 71.20 from the list of sections that a general license is issued without requiring the NRC to issue a package approval, so the list of sections would be revised to §§ 71.21 through 71.23.

Section 71.4 Definitions.

The definition of "contamination" would be added and would be consistent with the definition of contamination in DOT regulations at 49 CFR 173 and TS-R-1.

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

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

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

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

Section 71.6 Information collection requirements: OMB approval.

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

Section 71.14 Exemption for low-level materials.

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

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

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

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

Section 71.15 Exemption from classification as fissile material.

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

Section 71.17 General license: NRC-approved package.

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

Section 71.19 Previously approved package.

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

In redesignated § 71.19(b)(2), the phrase “[a]fter December 31, 2003” would be deleted. This would not change the requirement that packages used for a shipment to a location outside the United States would continue to be subject to multilateral approval as defined in the DOT regulations at 49 CFR 173.403, because all such shipments would occur after December 31, 2003.

Section 71.21 General license: Use of foreign approved package.

Paragraph 71.21(a) would be revised to update the reference to 49 CFR 171.12 to 49 CFR 171.23.

Paragraph 71.21(d) would be revised to clarify that the general licensee must comply with the requirements in § 71.21(d)(1) and (d)(2). Paragraph 71.21(d)(2) would be revised to delete the sentence regarding exemption from quality assurance provisions in subpart H for design, construction, and fabrication activities, because these requirements are not applicable to a general licensee. The general licensee would be required to comply with the quality assurance requirements in subpart H that do apply.

Section 71.31 Contents of application.

In paragraph 71.31(b), the reference to § 71.13 would be corrected 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 would be revised to remove the reference to the renewal of quality assurance program approvals. The section would be 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 would not have an expiration date and the NRC would revise the current quality assurance program approvals so that they would not have an expiration date. The renewal of a quality assurance program approval would be unnecessary. Paragraph 71.38(c) would also be revised for improved clarity.

Section 71.70 Incorporations by reference.

This section would 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” — and would describe the availability of the documents.

Section 71.75 Qualification of special form radioactive material.

In § 71.75(a)(5), the 1992 edition of ISO 9978 would be 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. This change would make 10 CFR part 71 consistent with the DOT requirements in 49 CFR 173, which incorporated ISO 9978:1992(E) in 2004.

In § 71.75(b)(2)(ii), the description of the billet used in the percussion test would be 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 § 71.75(b)(2)(iii), the description of the sheet of lead used in the percussion test would be 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 § 71.75(d), §§ 71.75(d)(1)(i) and (d)(1)(ii) would be added. In § 71.75(d), the 1999 edition of ISO 2919 would be incorporated by reference, replacing the reference to the 1980 edition of ISO 2919 for the alternate Class 4 impact test in § 71.75(d)(1)(i) and the alternate Class 6 temperature test in § 71.75(d)(2). The availability and other language incorporating this standard by reference is moved to § 71.70. Paragraph 71.75(d)(1)(ii) would allow 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 §§ 71.75(b)(1) and (b)(2), if the specimen weighs less than 500 grams.

Section 71.85 Preliminary determinations.

In § 71.75(a), (b), and (c), “licensee” would be replaced by “certificate holder.” The NRC experience is that these determinations are performed by the certificate holders who manufacture the package. This change would make the requirements consistent with current practice, because only certificate holders would have a quality assurance program approval that would allow them to conduct the required tests under an approved quality assurance program. Paragraph 71.85(d) would be added to address the responsibilities of licensees using a package for transportation. Although certificate holders would be required to make the preliminary determinations under § 71.85(a), (b), and (c), the licensee would be responsible for ensuring that these determinations have been made before their first use of the packaging.

Section 71.91 Records.

In § 71.91(a), the reference to § 71.10 would be corrected to § 71.14. This reference was not updated when § 71.10 was redesignated as § 71.14.

Section 71.101 Quality assurance requirements.

Paragraph 71.101(a) would be changed to clarify that certificate holders and applicants for a package approval are responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging. The last two sentences would be revised to be more precise and to provide clarity.

Paragraph 71.101(c)(2) would be changed to remove the reference to licensees in the first sentence. This would remove the overlap between the two paragraphs, by making it clear that licensees would notify the NRC before their first use of any package as required under § 71.75(c)(1) and certificate holders and applicants for a CoC would notify the NRC before the fabrication, testing, or modification of a package as required under § 71.75(c)(2).

Section 71.103 Quality assurance organization.

In § 71.75(a), footnote 2 would be removed. 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 section would be added to establish requirements that would apply to changes to quality assurance programs. It would allow some changes to a quality assurance program to be made without obtaining the prior approval of the NRC. Currently, all changes, no matter how insignificant, must be approved by the NRC before they can be implemented. These provisions would 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

would be required to get NRC approval before making changes to their quality assurance program that would reduce their commitments to the NRC.

Paragraph 71.106(a) would establish the requirements that would apply when a holder of a quality assurance program approval intends to make a change in their quality assurance program that would reduce their commitments to the NRC. The holder of a quality assurance program approval would be required to identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change would continue to satisfy the requirements of subpart H that apply.

Paragraph 71.106(a)(2) would require that each holder of a quality assurance program approval maintain quality assurance program changes as records. These records would need to be maintained as required in § 71.135.

Paragraph 71.106(b) would allow the holder of a quality assurance program approval to make changes to their quality assurance program that would not reduce their commitments to the NRC and identifies the changes that would not be considered as reducing their commitments to the NRC.

Paragraph 71.106(c) would require that records are maintained for any changes to the quality assurance program.

Section 71.135 Quality assurance records

This section would be 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 the changes to the quality assurance program as required by § 71.106 in the list of the types of records to be maintained.

Appendix A Determination of A_1 and A_2 .

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

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

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

Table A-1 would be revised to change the A_1 value for Cf-252 from 5.0×10^{-2} TBq to 1.0×10^{-1} TBq, and from 1.4 Ci to 2.7 Ci. Footnote h would be deleted and the following corresponding changes would be made: 1) the reference to footnote h would be removed from Cf-252, 2) the entry for molybdenum-99 (Mo-99) would be revised to identify footnote h instead of footnote i, and 3) footnote i would be redesignated as footnote h. Footnote c in the entry for Ir-192 would be moved, so that it is clear that it applies only to iridium in special form. Footnote c would also be revised to specifically state that the activity of iridium in special form may be determined through measurement at a prescribed distance from the source. Table A-1 would be revised to include values for Kr-79. The A_1 and A_2 values for Kr-79 correspond to the A_1 and A_2 values in TS-R-1 (2009 edition) and the specific activity would be 4.2×10^4 TBq/g

(1.1×10^6 Ci/g). The entry for Kr-81 would be revised to reflect that it is no longer the first entry for the isotopes of krypton. In addition, footnote a would be 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 would be 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 would be 1.0×10^3 Bq/g (2.7×10^{-8} Ci/g) and the value for the activity limit for exempt consignment would be 1.0×10^5 Bq (2.7×10^{-6} Ci). The activity limit for exempt consignment for Te-121m would be revised from 1×10^5 Bq (2.7×10^{-6} Ci) to 1×10^6 Bq (2.7×10^{-5} Ci). In footnote b, the chains for the parent radionuclides cerium-134 (Ce-134), Rn-220, Th-226, and U-240 are proposed to be removed, and a chain for Ag-108m is proposed to be added. This would make footnote b to Table A-2 consistent with footnote b to Table 2 in TS-R-1. Changes in the list in footnote b were not initially made to TS-R-1 when the nuclide-specific basic radionuclide values from the International Basic Safety Standards (IAEA Safety Series No. 115, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources) were adopted for transportation purposes, but were made in the 2005 edition of TS-R-1.

Table A-3 would be revised to reflect changes in TS-R-1. In the second entry, the descriptive phrase “only alpha emitting radionuclides are known to be present” would be 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” would be 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 would indicate 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.

V. Criminal Penalties

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

VI. Agreement State Compatibility

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 would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States’ and the NRC requirements. The NRC staff 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 proposed 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, above, and, thus, 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, as amended, or provisions of 10 CFR. These program elements are not adopted by the Agreement States.

The following table lists the parts and sections that would be 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.

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 | NRC | NRC |

| | | | | |
|-----------|---|--|---|---|
| | | approved package | | |
| 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: 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 | 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 thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137). |

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|--------------|--------------------------------|--------------------------------|---|---|
| | | | § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137). | |
| 71.101(b) | Revised Compatibility Category | Quality assurance requirements | <p>D—For those States which have no users of Type B packages—other than industrial radiography**.</p> <p>C—Those States which have users of Type B packages—other than industrial radiography**.</p> <p>**Note: 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 thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p> | <p>C</p> <p>**Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p> |
| 71.101(c)(1) | Revised Compatibility Category | Quality assurance requirements | <p>D—For those States which have no users of Type B packages—other than industrial radiography**.</p> <p>C—Those States which have users of Type B packages—other than industrial radiography**.</p> <p>**Note: 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 thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p> | <p>C</p> <p>**Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p> |
| 71.101(c)(2) | Revised | Quality assurance | NRC | NRC |

| | | | | |
|-----------|-------------------------------------|--------------------------------|---|--|
| | | requirements | | |
| 71.101(g) | Revised Compatibility Category Note | Quality assurance requirements | 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 § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137). | 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 thus would 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 thus would 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 thus would satisfy those sections referenced in 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 thus would satisfy those | 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 thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137). |

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| | | | 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 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 thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137). | 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 thus would 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 redesignate footnote i as footnote h. Add entry for Kr-79. | A ₁ and A ₂ Values for Radionuclides | [B] | [B] |
| 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, | Revise entries for | General Values for | [B] | [B] |

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|-----------|---|-----------------------------------|--|--|
| Table A-3 | column 1, "Contents," and add footnote a. | A ₁ and A ₂ | | |
|-----------|---|-----------------------------------|--|--|

¹ Where there would be a change in the assigned compatibility category, a compatibility category is assigned, or the content of the section has been significantly changed, a summary of the analysis is presented below. Changes in the assigned compatibility category are being 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 would 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," would 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," would be changed to make the requirements in § 71.85(a) through (c) apply to holders of a CoC. Paragraphs 71.85(a) through (c) would be 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) would be added and applies to licensees. Paragraph 71.85(d) would be 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," would be changed from Compatibility Category D to Compatibility Category C. In reaching an agreement with the NRC, the States would 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 proposing to designate 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 would be designated as compatibility category NRC. The States would not be 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 would 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 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 would be 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 would 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 would be 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 would be updated by changing § 71.12(b) to § 71.17(b).

The new § 71.106, “Changes to quality assurance program,” would apply to licensees and holders of, or applicants for, a CoC. The assigned compatibility category would be 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 would be performed by the NRC.

In § 71.135, the compatibility category would 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 would be 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 would be updated by changing § 71.12(b) to § 71.17(b).

VII. Availability of Documents

The following documents referenced in this Federal Register notice are available either through ADAMS or at the NRC PDR:

| Document | PDR | ADAMS | ADAMS Accession Number |
|--|-----|-------|------------------------|
| Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” | Yes | Yes | ML041770094 |
| NRC Information Notice 2002-035: “Changes to 10 CFR Parts 71 and 72 Quality | Yes | Yes | ML023520339 |

| | | | |
|---|-----|-----|-------------|
| Assurance Programs.” | | | |
| NRC Regulatory Issue Summary 2004-018: “Expiration Date for 10 CFR Part 71 Quality Assurance Program Plan Approvals.” | Yes | Yes | ML042160293 |
| NUREG/CR-5342, “Assessment and Recommendations for Fissile-Material Packaging Exemptions and General Licenses within 10 CFR Part 71,” July 1998. | Yes | Yes | ML12139A419 |
| Draft Environmental Assessment and Finding of No Significant Impact for the Proposed Rule Amending 10 CFR Part 71: Fissile Material Exemptions, Quality Assurance Programs, Harmonization with IAEA Transportation Requirements, and Other Transportation Safety Amendments | Yes | Yes | ML12187A109 |
| Regulatory Analysis for Proposed Rulemaking – Compatibility with IAEA Transportation Standards (10 CFR Part 71) | Yes | Yes | ML12187A110 |

VIII. 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). The NRC requests comments on the proposed rule with respect to the clarity and effectiveness of the language used. Comments should be sent to the NRC as explained in the ADDRESSES section of this document.

IX. 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 proposed rule, the NRC proposes using the consensus standards identified below and would incorporate them by reference. The NRC is proposing to adopt International Organization for Standardization, 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 International Organization for Standardization, ISO 9978:1992(E), "Radiation protection — Sealed radioactive sources — Leakage test methods," First Edition (February 15, 1992), for the leaktightness tests. The NRC invites comment on the applicability and use of other standards.

In other portions of this proposed 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 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.

X. 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 proposed rule because the Commission has concluded on the basis of an Environmental Assessment (ADAMS Accession No.

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

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

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

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 would be 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 would be allowed 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 would be very small impacts from these changes.

The determination of this Environmental Assessment is that there will be no significant impact to the public from this action. However, the NRC is providing an opportunity to comment on the Environmental Assessment. Comments on any aspect of the Environmental Assessment may be submitted to the NRC as indicated under the ADDRESSES section of this document.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined through ADAMS or at the NRC PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852.

XI. Paperwork Reduction Act Statement

This proposed 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). This proposed

rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Part 71, Fissile Material Exemptions, Quality Assurance Programs, Harmonization with International Atomic Energy Agency Transportation Requirements, and Other Transportation Safety Amendments.

The form number if applicable: Not applicable.

How often the collection is required: On occasion, for reports of changes reducing commitments to the NRC on quality assurance plans. Every 24 months for all changes to quality assurance plans.

Who will be required or asked to report: General licensees or users of packages, certificate holders and certificate applicants.

An estimate of the number of annual responses: 31

The estimated number of annual respondents: 250

An estimate of the total number of hours needed annually to complete the requirement or request: -1,700 hours (a decrease of 1,925 hours reporting + an increase of 100 third party disclosure hours and 125 hours recordkeeping)

Abstract: The NRC is proposing to amend its regulations for the packaging and transportation of radioactive material, including changes to information collections that would affect persons with a quality assurance program approved under 10 CFR part 71. Rather than submitting all quality assurance program changes to the NRC for approval, licensees, certificate holders, and applicants would only need to submit changes to their quality assurance program that would reduce their commitments to the NRC. They would be required to keep records of all quality assurance program changes and submit a report of these changes to the NRC every 24 months.

Burden on licensees would be reduced for renewing quality assurance programs, as future approvals of these programs would not expire.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule (or proposed policy statement) and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC public Web site:

<http://www.nrc.gov/public-involve/doc-comment/omb/index.html>, for 60 days after the signature date of this document.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]** to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Chad Whiteman, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0008), Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal rulemaking Web site <http://www.regulations.gov>, docket # NRC-

2008-0198. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. Comments can also be e-mailed to Chad_S_Whiteman@omb.eop.gov or submitted by telephone at (202) 395-4718.

XII. 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.

XIII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis (ADAMS Accession No. ML12187A110) on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES section of this document. The regulatory analysis is available for inspection through ADAMS or at the NRC PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852.

XIV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would 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 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 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 at 10 CFR 2.810. Also, a regulatory analysis was performed for this proposed rule. The regulatory analysis included an evaluation of the costs associated with the proposed requirements. The proposed rulemaking includes changes that would reduce the regulatory burden for licensees and certificate holders. Based on the information developed in the regulatory analysis, it is believed that there will not be significant economic impacts for a substantial number of small entities.

XV. 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 proposed rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required for this proposed rule, and the NRC did not prepare a backfit analysis for his proposed rule.

List of Subjects In 10 CFR Part 71

Hazardous materials transportation, Incorporation by reference, Nuclear materials, Packaging and containers, Radioactive materials, 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. 553; the NRC proposes to amend 10 CFR part 71 as follows:

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.

2. In § 71.0, paragraph (d)(1), the reference to “§§ 71.20 through 72.23” is revised to read “§§ 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 for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² for all other alpha emitters.

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

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

* * * * *

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

* * * * *

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

(1) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides which 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 material in which the activity is distributed throughout and the 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 would not exceed $0.1 A_2$; and

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

* * * * *

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

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

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

(3) It satisfies the requirements of § 71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before **[INSERT EFFECTIVE DATE OF FINAL RULE]** in accordance with the requirements of § 71.75(d) of this section in effect before **[INSERT EFFECTIVE DATE OF FINAL RULE]** 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, paragraph (b) is revised 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, paragraphs (a)(1) and (a)(2) are revised and paragraph (a)(3) is added 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 of this part.

* * * * *

6. In § 71.15, paragraph (d) is revised 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, paragraphs (c)(1) and (2) are revised 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 CoC, 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

* * * * *

8. In § 71.19, paragraphs (b) through (e) are redesignated as paragraphs (a) through (d), and redesignated paragraph (b)(2) is revised 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 regulations at 49 CFR 173.403.

* * * * *

9. In § 71.21, paragraphs (a) and (d) are revised 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 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.

10. In § 71.31, paragraph (b), the reference to “§ 71.13” is revised to read “§ 71.19”.

11. Section 71.38 is revised 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 this section. The materials can also be examined at the NRC Public Document Room, O1-F21, 11555 Rockville Pike, Rockville, Maryland 20852 or at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-5610; e-mail: Library.Resource@nrc.gov. The materials are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 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) International Organization for Standardization, 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) International Organization for Standardization, 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, paragraphs (a)(5), (b)(2)(ii), (b)(2)(iii), (d)(1), and (d)(2) are revised 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 (.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, paragraphs (a), (b), and (c) are revised and paragraph (d) is added to read as follows:

§ 71.85 Preliminary determinations.

* * * * *

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

(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the certificate holder shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure;

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

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

15. In § 71.91, paragraph (a). the reference to “§ 71.10” is revised to read “§ 71.14”.

16. In § 71.101, paragraphs (a) and (c)(2) are revised 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 which apply to design, fabrication, testing, and modification of packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements which apply to its use of a packaging for the shipment of licensed material subject to this subpart.

* * * * *

(c) * * *

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

* * * * *

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

§ 71.103 Quality assurance organization.

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

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 would 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.

(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 which is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

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

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

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

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

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

19. Section 71.135 is revised to read as follows:

§ 71.135 Quality assurance records.

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

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

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

APPENDIX A TO PART 71 — DETERMINATION OF A₁ AND A₂

* * * * *

IV. * * *

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

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

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

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

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

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

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

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

Where B(i) is the activity of radionuclide i as special form radioactive material, A₁(i) is the A₁ value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A₂(j) is the A₂ value for radionuclide j.

d. Alternatively, the A₁ 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.a. * * *

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. 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.

* * * * *

21. In appendix A to part 71, Table A-1, the entry for Kr-79 is added, the entry for Cf-252 is amended, the entry for Kr-81 is amended, the entry for Ir-192 is amended by moving footnote c to the entries for A₁ values for Ir-192 and revising footnote c, and the entry for Mo-99 is amended by removing footnote i and adding footnote h, and footnote h is revised, to read as follows:

* * * * *

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

^a A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less

than 10 days, as listed in the following:

| | |
|---------|-----------------|
| Mg-28 | Al-28 |
| Ca-47 | Sc-47 |
| Ti-44 | Sc-44 |
| Fe-52 | Mn-52m |
| Fe-60 | Co-60m |
| Zn-69m | Zn-69 |
| Ge-68 | Ga-68 |
| Rb-83 | Kr-83m |
| Sr-82 | Rb-82 |
| Sr-90 | Y-90 |
| Sr-91 | Y-91m |
| Sr-92 | Y-92 |
| Y-87 | Sr-87m |
| Zr-95 | Nb-95m |
| Zr-97 | Nb-97m, Nb-97 |
| Mo-99 | Tc-99m |
| Tc-95m | Tc-95 |
| Tc-96m | Tc-96 |
| Ru-103 | Rh-103m |
| Ru-106 | Rh-106 |
| Pd-103 | Rh-103m |
| Ag-108m | Ag-108 |
| Ag-110m | Ag-110 |
| Cd-115 | In-115m |
| In-114m | In-114 |
| Sn-113 | In-113m |
| Sn-121m | Sn-121 |
| Sn-126 | Sb-126m |
| Te-127m | Te-127 |
| Te-129m | Te-129 |
| Te-131m | Te-131 |
| Te-132 | I-132 |
| I-135 | Xe-135m |
| Xe-122 | I-122 |
| Cs-137 | Ba-137m |
| Ba-131 | Cs-131 |
| Ba-140 | La-140 |
| Ce-144 | Pr-144m, Pr-144 |
| Pm-148m | Pm-148 |
| Gd-146 | Eu-146 |
| Dy-166 | Ho-166 |
| Hf-172 | Lu-172 |
| W-178 | Ta-178 |
| W-188 | Re-188 |
| Re-189 | Os-189m |
| Os-194 | Ir-194 |
| Ir-189 | Os-189m |
| Pt-188 | Ir-188 |

| | |
|---------|--|
| Hg-194 | Au-194 |
| Hg-195m | Hg-195 |
| Pb-210 | Bi-210 |
| Pb-212 | Bi-212, Tl-208, Po-212 |
| Bi-210m | Tl-206 |
| Bi-212 | Tl-208, Po-212 |
| At-211 | Po-211 |
| Rn-222 | Po-218, Pb-214, At-218, Bi-214, Po-214 |
| Ra-223 | Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207 |
| Ra-224 | Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212 |
| Ra-225 | Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209 |
| Ra-226 | Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214 |
| Ra-228 | Ac-228 |
| Ac-225 | Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209 |
| Ac-227 | Fr-223 |
| Th-228 | Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212 |
| Th-234 | Pa-234m, Pa-234 |
| Pa-230 | Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214 |
| U-230 | Th-226, Ra-222, Rn-218, Po-214 |
| U-235 | Th-231 |
| Pu-241 | U-237 |
| Pu-244 | U-240, Np-240m |
| Am-242m | Am-242, Np-238 |
| Am-243 | Np-239 |
| Cm-247 | Pu-243 |
| Bk-249 | Am-245 |
| Cf-253 | Cm-249 |

* * * * *

^c The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

* * * * *

^h $A_2 = 0.74$ TBq (20 Ci) for Mo-99 for domestic use.

* * * * *

22. In appendix A, Table A-2, the entry for Kr-79 is added, the entries for Kr-81 and Te-121m are amended, and footnote b is revised to read as follows:

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

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

* * * * *

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

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

* * * * *

23. In appendix A to part 71, Table A-3 is revised to read as follows and footnote a is added.

* * * * *

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

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

* * * * *

Dated at Rockville, Maryland, this _____ day of _____, 2012.

For the Nuclear Regulatory Commission.

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

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

U.S. Nuclear Regulatory Commission

November 2012



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EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is proposing to amend its regulations for the packaging and transportation of radioactive material. These amendments would 1) conform the NRC regulations to the 2009 edition of the International Atomic Energy Agency's (IAEA) international transportation standards, 2) maintain consistency with changes in the DOT regulations, and 3) make other changes to the requirements for the packaging and transportation of radioactive material. These changes are necessary to maintain a consistent regulatory framework for the transportation and packaging of radioactive material. In addition, these changes would make the regulation of Quality Assurance (QA) programs more efficient by removing the requirement for prior approval of QA programs for users of packages, allowing changes that do not change commitments to be made without prior NRC approval, and removing the requirement to renew a QA program.

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

The RA makes the following key findings:

Total cost to Industry: The proposed rule would result in a one-time cost to the industry of approximately \$95,000 and would have a total annual savings of about \$112,000.

Total cost to the NRC: The rule would result in a one-time cost to the NRC of approximately \$367,000, followed by annual cost savings of approximately \$22,000.

Total cost to Agreement States: Agreement States would be required to review proposed rule language and to amend its regulations consistent with the final rule. The rule would result in a one-time cost to Agreement States of approximately \$1.8 million.

Decision Rationale: Based on the analysis described below, the NRC concludes that the proposed rule, if implemented, would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency and to provide benefits to licensees and to the NRC and Agreement States with a small change to measures of impacts to public health and safety.

The proposed rule is planned for publication in the *Federal Register* in October 2012. Following a public comment period and several months to review the public comments, the NRC will revise the proposed rule and publish a final rule, as appropriate.

ABBREVIATIONS

| | |
|--------|--|
| ADAMS | Agencywide Documents Access and Management System |
| AS | Agreement States |
| CFR | <i>Code of Federal Regulations</i> |
| 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 |
| 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" |

1. INTRODUCTION

The U.S Nuclear Regulatory Commission (NRC) is planning to publish a proposed rule amending its regulations for packaging and transportation of radioactive material. These amendments would make NRC regulations consistent with 2009 revisions to the International Atomic Energy Agency's (IAEA's) transportation standards, "Regulations for the Safe Transport of Radioactive Material," (TS-R-1). The NRC co-regulates domestic transportation of radioactive material with the U.S. Department of Transportation (DOT). DOT regulations regarding transportation of radioactive materials are in Title 49 of the *Code of Federal Regulations* (49 CFR) Parts 107, 171-180, and 390-397. The NRC and the DOT are publishing proposed rules with the dual purpose to achieve compatibility with IAEA's transportation standards and to improve regulatory efficiency by maintaining a consistent regulatory framework. The NRC is also proposing to make other changes which do not affect compatibility with the IAEA TS-R-1 or the DOT hazardous material regulations as discussed in more detail below.

This Regulatory Analysis (RA) presents background material, rulemaking objectives, alternatives, and input assumptions, and describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

1.1 Statement of the Problem and Objective of the Rulemaking

The proposed amendments would revise NRC regulations for the packaging and transportation of radioactive material to: 1) make the NRC regulations compatible with the 2009 edition of the IAEA TS-R-1; 2) maintain consistency with changes in the DOT regulations; and 3) make other changes to the requirements for the packaging and transportation of radioactive material, which do not affect compatibility with the IAEA's TS-R-1 or the DOT's hazardous material regulations.

The IAEA revises its transportation standards periodically to reflect acquired knowledge and experience. The NRC periodically updates its transportation regulations at 10 CFR Part 71 to reflect the changes in the IAEA's transportation standards.

One objective of the proposed rule would be to achieve compatibility with the IAEA's transportation standards. DOT is proposing the same amendments in its proposed rule to achieve compatibility with TS-R-1. Amendments to achieve compatibility are referred to in this document as the "IAEA-DOT compatibility" alternative. The amendment would allow a licensee who transports special form radioactive material, and who is using a specimen to simulate radioactive material contained in a sealed capsule, to use an alternative impact test currently allowed by the IAEA in TS-R-1 as one of the acceptable impact tests cited in the regulations. The amendments in the "IAEA-DOT compatibility" alternative are expected to have little impact on the public and on licensees, and will have only a minor impact on the NRC due to the one-time implementation cost to prepare the final rule, and amend regulations. In November 2012, the IAEA issued new standards for the safe transport of radioactive material and designated them as "Specific Safety Requirements Number SSR-6" (SSR-6). This rulemaking does not incorporate the 2012 IAEA changes, which will undergo a comprehensive review by the NRC staff to determine if additional changes to 10 CFR Part 71 are warranted.

Another objective of the proposed rule is to increase the efficiency of the oversight of Quality Assurance (QA) program. The NRC requires licensees to comply with their own NRC approved

QA programs. The NRC is proposing changes that would 1) establish a mechanism to allow some changes to be made in an approved QA program without obtaining prior NRC approval and 2) remove the requirements for renewal of QA program approvals. These changes would increase the efficiency of the NRC oversight of quality assurance by removing the need for holders of the QA program approval to obtain prior NRC approval of amendments to QA program descriptions that do not reduce the commitments in an approved QA program. This would allow holders of QA program approvals to implement changes more quickly.

The proposed amendments to 10 CFR Part 71 that would permit holders of the QA program approval to make changes to their QA program without NRC approval are modeled after those in 10 CFR Part 50. Holders of a QA program approval would only need to submit to the NRC for prior approval those changes to their QA program that would reduce commitments made to the NRC. Under the proposed rule, holders of a QA program approval would be required to report to the NRC at least every 24 months any changes they have made to their approved QA program.

1.2 Background

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 instruments 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." There is a need for the NRC and the DOT to harmonize¹ domestic transport regulations with changes made to the IAEA's TS-R-1 over the past several years. These changes can be implemented with slight cost to the public and domestic regulatory authorities responsible for implementing the proposed changes.

A second set of changes is being proposed to eliminate unnecessary administrative requirements that require licensees to submit documents to the NRC for approval. The current regulations require holders of a QA program approval to obtain prior NRC approval of every change to their QA program, of which some are administrative, such as the transfer of functional responsibility within organizations and generic organizational position titles. The proposed rule would amend this by making the 10 CFR Part 71 transportation QA requirements similar to the requirements for making changes to a QA program that apply to 10 CFR Part 50 licensees. The amended transportation requirements would require QA program changes to be submitted to

¹ The regulations in the IAEA's TS-R-1 represent an accepted set of requirements that are considered to provide a high-level of safety in the packaging and transportation of radioactive materials and provide a basis and framework that facilitates the development of internationally-consistent regulations. Internationally-consistent regulations for the transportation and packaging of radioactive material reduce impediments to trade, facilitate international cooperation, and, when the regulations provide a high-level of safety, can reduce risks associated with the import and export of radioactive material. Harmonization represents the effort to increase the consistency or compatibility between national regulations and the internationally-accepted requirements, within the constraints of an existing national legal and regulatory framework.

the NRC only if the change results in a reduction in the commitments made to the NRC compared to the currently approved QA program. This change is being made to promote savings on the part of industry and regulators. The proposed amendments would require holders of the QA program approval to report to the NRC at least every 24 months any changes they have made to their approved QA program.

2. IDENTIFICATION OF ALTERNATIVE APPROACHES

The following sections describe the regulatory options that the NRC is considering in order to meet the rulemaking objectives identified in the previous section. Section 3 presents a detailed analysis. The NRC considered three alternatives for the proposed rule, described in the following three sections. The full list of changes which 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

The No-Action alternative would maintain the status quo. Under the No-Action Alternative, 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 proposed rule would impose; however, it would allow greater divergence between the international standards and the domestic regulations. Radioactive material is imported and exported. Consistency between domestic and international transportation regulations facilitates international commerce. Differences in domestic and international regulations can make it more complicated and expensive to import or export radioactive material and inhibit trade. There would be no changes made that would 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 the 2009 edition of the IAEA's TS-R-1 and with changes proposed by the DOT.

- Section 71.4, Definitions. The definition of contamination would be added. The definitions for "Criticality Safety Index (CSI)," "Low Specific Activity (LSA) material," "special form radioactive material," and "uranium — natural, depleted, enriched" would be revised.
- Section 71.14, Exemption for low-level material. Paragraph (a) would be changed to revise the exemption to include natural material and ore that has been processed to qualify for the exemption. Paragraph (a)(3) would be 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 used to define contamination.
- Paragraph 71.75(d), Qualification of special form radioactive material. This change would 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 would 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, A₁ and A₂ Values for Radionuclides. The table would be revised by adding an entry for krypton-79 (Kr-79); revising entries for californium-252, iridium-192, krypton-81, and molybdenum-99; and revising footnotes to be consistent with the IAEA’s TS-R-1.
- Appendix A, Table A-2, Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides. The table would be revised by adding an entry for Kr-79, revising the entry (values) for tellurium-121m (Te-121m), and revising footnote b.

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

This alternative includes 1) all of the proposed changes comprising Alternative 2, which would amend the NRC regulations to increase consistency and compatibility with the 2009 edition of the IAEA’s TS-R-1 safety standards, and maintain consistency with changes proposed by the DOT; and 2) implement NRC-initiated changes.

The changes listed below are consistent with Alternative 3 to Compatibility with IAEA Transportation Standards in 10 CFR Part 71.

- 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) would be revised to require the material to be distributed homogeneously and not form a lattice arrangement.
- Section 71.38, Renewal of a certificate of compliance. This section would be retitled and revised to remove references to renewals of QA program approvals, which would no longer be necessary.
- Section 71.85, Preliminary determinations. This section would be revised to replace “licensee” with “certificate holder” in paragraphs (a), (b), and (c); and paragraph (d) would be 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 would be added to revise the process for holders of a QA program approval to make changes to an approved QA program and would require periodic reporting of those changes that do not require prior NRC approval.

- Section 71.135, Quality assurance records. This section would be 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. The costs and benefits 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 VALUES AND IMPACTS

This section examines the values (benefits) and impacts (costs) expected to result from the proposed 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 proposed amendments.

Throughout this RA, various labor rates are used. These labor rates are used consistently for all of the issues. The bases for the labor rates are described below. Labor rates for licensees — including holders of a Certificate of Compliance (CoC) or a QA program approval and applicants — and Agreement States were obtained from National Wage Data databases 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 was determined. The hourly cost was determined by multiplying the hourly labor rate by 1.5 to account for benefits (insurance premiums, pension, and legally required benefits). Nationwide mean hourly labor rates are used, because exact hourly rates are difficult to obtain and may not be sufficiently recent. For licensee labor rates, \$73.20/hour (\$48.80/hour X 1.5) is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, “Nuclear Engineers.” For all Agreement State labor rates, \$60.80/hour (\$40.53/hour X 1.5) is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, “Lawyers.”

The NRC labor rates are determined per the calculation methodology in Abstract 5.2, “NRC Labor Rates,” of NUREG/CR-4627, Rev.1, Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses.” Currently, the hourly labor rate for the NRC is \$119.

The estimation of costs for rulemaking is based on professional NRC staff full-time equivalent (FTE). Based on actual data from the NRC time and labor system, the number of hours in 1 year that directly relate to implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hourly rate is based on 1,451 hours per year.

The estimated costs for the Agreement States to amend and implement changes to their regulations are based on the number of productive hours in one year, as described in the Office of Management and Budget (OMB) Circular A-76, “Performance of Commercial Activities”, which is 1,776. The actual number of productive hours per year is likely to vary from state to state and no specific data are available. Costs for the Agreement States are calculated using the 1,776 productive hours per year from OMB Circular A-76 per FTE.

3.1 Identification of Affected Attributes

This section lists the significant attributes for this proposed rulemaking and describes the expected changes in the context of these attributes. The benefits and costs for each attribute are quantified using the methodology described in Section 3.2. Those attributes that are not expected to be affected by the proposed amendments are listed at the end of the Section 3.1. NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," identifies a set of attributes to be evaluated. All of the attributes listed in NUREG/BR-0184 are addressed below. No additional attributes that would inform the evaluation of values and impacts for this proposed rulemaking were identified.

- **Industry Operation:** The NRC is proposing to make changes that would make the regulation of QA programs more efficient. The NRC is proposing to issue QA program approvals that would not expire, removing the need for the approval to be renewed, and would revise the current QA program approvals so that they would not expire. The NRC is also proposing to allow those changes that do not reduce the commitments in an approved QA program to be made without prior NRC approval. Additional material might qualify for the exemption of low-level radioactive material, which would facilitate the transportation of these materials and reduce shipping costs. In aggregate, industry operations are anticipated to be improved, resulting in savings.
- **Industry Implementation:** If the proposed action is adopted/promulgated the licensee 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. Changes to 10 CFR 71.75(d), which would 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 the licensee to incur a one-time cost for the purchase of equipment.
- **NRC Implementation:** Under the proposed action, the NRC would publish the draft rule for public comment. The NRC plans to consider any public comments received, develop a final rule and amend guidance to be consistent with the new requirements. With the publication of the final rule, the NRC would re-issue QA program approvals with no expiration date. The NRC would 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. Under Alternative 2 and Alternative 3, the NRC would need to update guidance.
- **Other Governments:** Agreement States would 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 State governments will incur one-time costs to amend regulations to implement Alternative 2 or Alternative 3, and annual savings due to improved regulatory efficiency from Alternative 3.

The U.S. Department of Energy (DOE) certifies their own packages and 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 would need to comply with proposed amendments to the fissile material exemption.

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.

- **Regulatory Efficiency:** The proposed 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 proposed 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 would 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 would 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 proposed rulemaking would modify 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 would not need to apply to renew their approval and the NRC would not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC would re-issue QA program approvals with no expiration date.

- **Environmental Considerations:** The proposed rulemaking would involve changes that could have environmental impacts. The proposed amendments would 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 would increase the number of shipments of low specific activity radioactive material that would be exempt from the NRC and the DOT transport regulations (i.e., would 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 impacts, the NRC determined that there would be no significant impact to the public from the proposed amendments.
- **NRC Operations.** Holders of a QA program approval would not need to apply to renew their approval and the NRC would not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC would re-issue QA program approvals with no expiration date. The NRC would need to review the biennial reports of changes to QA programs that do not reduce commitments to the NRC. The proposed action would 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)
Public Health (Routine)
Antitrust Considerations
Improvements in Knowledge

Offsite Property
Onsite Property
General Public

Occupational Health (Accident)
Occupational Health (Routine)
Safeguards and Security

Section 4 presents the results, in constant 2012 dollars. The results are shown for the one-time costs (or benefits) and the annual operating expense (or savings) to implement Alternatives 2 and 3. The total benefits and costs over the 10-year analysis period are estimated using 7 percent and 3 percent real discount rates.

The estimated total cost for Alternative 3 is approximately \$1.1 million and \$1.3 million, discounted at 3 percent and 7 percent, respectively for the preferred approach. The 3 percent discounted value is less than the 7 percent discount value because of the large amount of annual cost savings to the industry and the NRC.

3.2 Analytical Methodology

This section describes the methodology used to analyze the values and impacts associated with the proposed rule. The values (benefits) consist of any desirable changes in the affected attributes. The impacts (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 proposed rule have been obtained from NRC staff.

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, 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 and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on long-term 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

NRC seeks public comments on the accuracy of these RA assumptions and on the validity of the proposed rule's value and impact estimation methods. The NRC has specifically requested comments from the public on this assumption in the RA.

The RA includes assumptions and estimates. The NRC staff relied on referenced sources for the assumptions and estimates when these were available. In some cases, the NRC was not aware of any input data and in these cases the NRC staff made an estimate based on best professional judgment. These are noted as "staff judgment" in the descriptions of the input data. The NRC seeks public comments on the accuracy of the assumptions and estimates used in this RA, and on the validity of the method to estimate values and impacts of the proposed rule.

3.2.1 General Assumptions

Costs are expressed in 2012 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 2012 discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, Rev. 4.

The [NRC staff's] general input assumptions for the analysis are discussed below.

- 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 proposed amendments. Currently, the NRC hourly labor rate is \$119.
- The NRC staff determined Licensee labor rates using 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 staff determined Agreement State labor rates using 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., \$119/hour.
- The NRC staff estimates there are 290 entities – 210 general licensees or users of packages, 40 certificate holders/applicants for certificate holders, 37 Agreement States, DOE, DOT, and CRCPD – would be directly impacted by the proposed amendments. The CRCPD impacts – development of Suggested State Regulations for Control of Radiation – would be a subset of, and considered as part of, the Agreement State impacts, because it would be Agreement State staff working to develop the Suggested State Regulations for Control of Radiation.

- The time period for the analysis is 10 years. Renewals of QA program approvals are required every 10 years. The 10-year period for the analysis was selected to cover one complete QA program approval renewal period.
- Estimates were made for one-time implementation costs. It is assumed that the costs will be incurred in the first year of the analysis. 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 would not be discounted).
 - There are one-time implementation costs assumed for the NRC and the Agreement States.
 - One time implementation costs for the transportation industry may be incurred in response to amendments to 10 CFR Part 71. The area's most likely to contribute to one-time implementation costs include: 1) exemption of low-level materials, 2) preliminary determinations, 3) qualification of special form material; and 4) quality assurance.
- 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 would amend two sets of 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 NRC and the Agreement States. The specific [NRC staff] assumptions for Alternative 2 are:

- 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 would incur costs associated with this effort. It is estimated that 50 percent of licensees would 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 would be made to review the changes in the regulations. The proposed rulemaking includes 24 proposed amendments. It is estimated that an average of 2 hour per licensee or certificate holder would be spent reviewing the changes, for a total of approximately \$35,000.
- The changes to 71.14(a) would 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 would not be

shipped for the use of its radionuclides. Licensees would need to ensure correct labeling and placarding for their shipments. This would 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 would be unaffected by this change. It is assumed that about 2 percent of licensees (five licensees) would 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 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 after being adjusted to better approximate the amount of material affected by the proposed 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 proposed 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). 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 would qualify for the exemption, the volume of material and the number of shipments would include the shipment of some material not specifically evaluated.
- It is estimated that approximately 12,000 metric tons of material is shipped by rail in approximately 125 railroad cars (or shipments).
- It is assumed that annual fees and permits would not be affected by this change, because some material would still be shipped as class 7 (radioactive) hazardous material.
- It is estimated that approximately \$500 per shipment would be saved, because the material would not be shipped as radioactive material.

- The NRC is proposing to incorporate 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.” 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 licensee would obtain a copy of the ISO standards. It is also assumed that they would acquire the standards at the non-member rate. These estimates would be conservative in estimating the costs. Purchasing the two standards from the distributor in the U.S. would cost each licensee \$200.
 - The NRC staff estimates there are 60 Class 4 and Class 6 tests performed each 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 would cost \$500 for each licensee who acquires the equipment. It is assumed that about 5 percent of the licensees (rounded up to 5 licensees) would purchase the equipment, for a total cost of \$2,500.
 - It is estimated that licensees would perform 50 Class 5 impact tests each year instead of the Class 4 impact at an equivalent savings of the costs for one labor hour per test, for a total savings of \$3,660.

Other changes would amend certain values in 10 CFR Part 71, Tables A-1, A-2, and A-3, Appendix A. See chart in Appendix 1 for a summary of the proposed changes and estimates for the effect of each change. These changes would result in an estimated net savings of \$20,000 annually for the industry.

The NRC will require approximately 2031 labor hours (1.4 FTE) to develop a final rule and update guidance. The NRC would develop the final rule following the close of the public comment period for the proposed rule. The effort to develop the final rule and update the guidance is modeled as a one-time labor cost.

- 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 proposed rule language and to amend regulations consistent with the final rule. An estimate of 16,428 labor hours for all 37 Agreement States is made and modeled as a one-time labor cost.
- No quantitative costs or benefits accrue to industry as a result of the Alternative 2 regulatory changes.

The input assumptions for Alternative 2 are in Appendix 1.

3.2.3 Specific Assumptions for Alternative 3

Under Alternative 3, the NRC would make the changes identified above for Alternative 2 and other conforming changes. The specific assumptions for Alternative 3 are listed below.

- The proposed changes to 10 CFR 71.15(d) would revise the exemption that applies to uranium enriched to a maximum of one percent to require the material to be distributed homogeneously and not form a lattice arrangement. The type of material that would be affected by this change is more likely to be possessed by the DOE than by a licensee. It is not typically shipped. Therefore, it is assumed that only the DOE would ship this material.
 - Shipments of material that would be affected by the changes to the fissile material exemption for uranium enriched to a maximum of one percent are unlikely and estimated to occur once every 10 years. Accordingly, the NRC estimates there will be one shipment in the 10-year period. It is assumed that this shipment would occur midway through the analysis period.
 - The effect of this amendment would be to preclude uranium enriched to a maximum of one percent that is not distributed homogeneously or that forms a lattice arrangement from being shipped under the fissile material exemption. It is assumed that the material would be able to be shipped under a general license for fissile material, which would 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 would take 40 hours. It is assumed that the CSI would not exceed 100, so the shipment would not need to be shipped using separate conveyances.
- The NRC is proposing to amend 10 CFR 71.38 to remove the need for QA program approvals to be renewed. These proposed changes would result in a savings for the NRC, general licensees, and holders of, or applicants for, a CoC. These are related to changes to 10 CFR 71.106.
- It is estimated that an average of 25 QA program approvals would not be required each year. Holders of the QA program approval would 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 would 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 would need to issue new QA program approvals that would not have an expiration date. The NRC estimates that issuing the replacement QA program approvals would require 40 hours to complete.
- The NRC is proposing to add 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 proposed requirements in 10 CFR 71.106(a) would result in a savings for holders of a QA program approval and the NRC. Holders of a QA program approval would 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 would benefit from the proposed amendments each year. It is estimated that, on average, 25 labor hours would 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 proposed amendments in 10 CFR 71.106(b) would 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. The NRC estimates that QA program approval holders will spend 1 hour every 2 years to comply with this proposed requirement. The NRC estimates it will spend 1 hour to review each submittal.
 - Holders of a QA program approval would be required to maintain records created in response to the proposed changes to § 71.106. The NRC estimates that each QA program approval holder would 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 would require 50 percent more staff hours than the effort required to implement Alternative 2. This means about 3,047 labor hours will be required of the NRC and about 24,642 labor hours by the Agreement States. This is modeled as a one-time labor cost.

The estimates for the effect of each change for Alternative 3 are in Appendix 2.

3.2.4 Data on Affected Entities

The analysis makes the following assumptions regarding the entities affected:

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

The NRC staff would develop the rule package and revise guidance to accommodate the requirements that would be added or modified by the rulemaking process.

4. PRESENTATION OF RESULTS

This section presents results of values and impacts that are expected to be derived from the proposed 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 values in other attributes, such as Improvements in Knowledge, Regulatory Efficiency, Environmental Considerations, and Public Confidence, but these are not quantified because they are expected to be small. The quantified values are presented in constant 2012 dollars, for both implementation and annual operating expenses. The impact of the proposed 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 2012 dollars. Alternative 1, the No-Action Alternative, provides a baseline against which the other two alternatives are assessed.

4.1 Summary of Results

This section presents results of the benefits and costs that are expected to be derived from the proposed rule. To the extent that the affected attributes could be analyzed quantitatively, the costs have been calculated and are presented below. Some values and impacts are addressed qualitatively for reasons discussed in Section 3.2. Exhibits 3-1 and 3-2 summarize these results.

Table 4-1 presents the net impact of the proposed 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 | \$1,008,576 | Alternative 2 | \$1,104,488 |
| Alternative 3 | \$1,142,677 | Alternative 3 | \$1,344,380 |

There are no costs or benefits associated with Alternative 1, the No Action Alternative. The estimated cost of approximately \$1 million (3 percent discount rate) for Alternative 2 is to implement the proposed 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 due to:

- The removal of the requirement to submit QA related information to the NRC, which the NRC does not need, equal 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.

The cost to the NRC and Agreement States to implement amended regulations is about 50 percent higher for Alternative 3 compared to Alternative 2 because of the larger scope of activity.

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 percent discount rate.

Table 4-2: Estimated Values and Impacts by Attribute for Alternative 1, 2 and 3

| | Alternative 1 | Alternative 2 | Alternative 3 |
|-------------------------|---------------|---------------|---------------|
| Industry Implementation | \$0 | \$95,136 | \$95,136 |
| Industry Operation | \$0 | -\$543,033 | -\$954,207 |
| NRC Implementation | \$0 | \$241,689 | \$367,365 |
| NRC Operation | \$0 | \$0 | -\$187,792 |
| Agreement States | \$0 | \$1,214,784 | \$1,822,176 |
| Total | \$0 | \$1,008,576 | \$1,142,677 |

Table 4-3 summarizes the costs by entity, over a 10-year analysis period.

Table 4-3: Summary of Values and Impacts for Alternatives 2 and 3

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 | \$367,365 | -\$22,015 | \$179,573 | \$212,741 |
| Total | \$2,284,677 | -\$133,877 | \$1,142,677 | \$1,344,380 |

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 | \$241,689 | \$0 | \$241,689 | \$241,689 |
| Total | \$1,551,849 | -\$63,660 | \$1,008,576 | \$1,104,488 |

Table 4-4 shows all of the amendments that are included in the proposed rule, and whether or not the amendment is estimated as a cost (or savings) to industry and to regulators, or is insignificant and not included in the cost-benefit calculations.

Table 4-4: Proposed Rule Amendments and Significance in the Cost-Benefit Analysis

| 10 CFR Part 71 Proposed Amendment Description | | Cost of amendment estimated as a licensee and/or NRC cost and included in cost-benefit analysis | Cost of amendment NOT estimated as a licensee and/or NRC cost and NOT included in cost-benefit analysis |
|--|---|---|---|
| 71.0 | Purpose and Scope. A section is deleted from the list of sections for which general licenses are issued without a required NRC package approval. | | • |
| 71.4 | Definitions. Add definition of “contamination.” Revise definitions of “Criticality Safety Index (CSI),” “Low Specific Activity (LSA) material,” “special form radioactive material,” and “uranium – natural, depleted, enriched.” | | • |
| 71.6 | Information Collection Requirements: OMB Approval. A new section that would have an information collection would be added. | | • |

| | | | |
|---------------------|---|---|---|
| 71.14(a)(2) and (3) | Exemption for low-level materials. The exemption for natural material and ores containing naturally occurring radionuclides would be revised to include material that has been processed, but is not intended to be processed for the use of the radionuclides. A reference to Table A-3 would be added. An exemption would be added for non-radioactive solid objects which have radioactive substances present on its surfaces, provided that the quantity of radioactive substances are below the quantity used to define contamination. | • | |
| 71.15(d) | Exemption for classification as fissile material. The exemption that applies to uranium enriched to a maximum of one percent would be revised to require the material to be distributed homogeneously and not form a lattice arrangement. | • | |
| 71.17(c) | General license: NRC-approved package. Would be revised to clarify that the general licensee must comply with the requirements in paragraphs (c)(1) through (c)(3). | | • |
| 71.19(a) | Previously approved package. Paragraphs would be redesignated and paragraph (b)(2), which would be redesignated as paragraph (a)(2), would be changed to delete the phrase "December 31, 2003". | | • |
| 71.21(a) | General license: Use of a foreign approved package. This paragraph would be revised to update the reference to 49 CFR 171.12. | | • |
| 71.21(d) | General license: Plutonium-beryllium special form material. This paragraph would be revised to clarify that the general licensee must comply with the requirements in paragraphs (d)(1) and (d)(2). | | • |

| | | | |
|-------------|---|----------------|----------------|
| 71.31 (b) | Contents of application. Would be revised to update a reference to another section. | | • |
| 71.38 | Renewal of a certificate of compliance. Would be retitled and revised to remove references to renewals of quality assurance program approvals, which would no longer be necessary. | • | |
| 71.70 | Incorporation by reference. This section would be added to consolidate the incorporation by reference language; the costs associated with the consensus standards that would be incorporated by reference are discussed as part of 10CFR 71.75. | | • |
| 71.75(a)(5) | Qualification of special form radioactive material. Would incorporate by reference ISO 9978 for the alternate leak test methods. | | • ¹ |
| 71.75(b)(2) | Qualification of special form radioactive material. Paragraphs (b)(2)(ii) and (b)(2)(iii) would be revised to make corrections in the description of the billet and the lead sheet. | | • |
| 71.75(d) | Qualification of special form radioactive material. Would incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and would allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams. | • ² | • |
| 71.85 | Preliminary determinations. Would be revised to make certificate holders responsible for making preliminary determinations and durably marking the package. Licensees would be responsible for ensuring that the preliminary determinations have been made. | | • ³ |

| | | | |
|--------------------------|--|---|---|
| 71.91(a) | Records. Would correct the reference from 10 CFR 71.10 to 10 CFR 71.14. | | • |
| 71.101(a) | Quality assurance requirements. Would clarify the responsibilities of certificate holders and licensees to reflect the activities that they conduct and would clarify when the NRC is to be notified that a previously approved quality assurance program is to be applied to transportation activities. | | • |
| 71.101(c)(2) | Quality assurance requirements. Would clarify that this section only applies to certificate holders and applicants. | | • |
| 71.103(a) | Quality assurance organization. Would delete a footnote, which is considered unnecessary. | | • |
| 71.106 | Changes to quality assurance program. Would be 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. | • | |
| 71.135 | Quality assurance records. This section would be revised to include changes made to an approved quality assurance program as a quality assurance record. | • | |
| Appendix A, paragraph IV | Determination of A_1 and A_2 . Clarifications and corrections would be made to the process for calculating values for A_1 and A_2 . | | • |
| Appendix A, paragraph V | Determination of A_1 and A_2 . Direction would be provided for calculating exempt activity concentration and exempt consignment activity for certain mixtures of radionuclides. | | • |

| | | | |
|--------------------------|--|---|---|
| Appendix A, Table A-1 | A ₁ and A ₂ Values for Radionuclides. Would be revised by adding entries, revising entries, and revising footnotes. | • | |
| Appendix A, Table A-2 | Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides. Would be revised by adding an entry for Kr-79, revising the entry (values) for Te-121m, and revising footnote b. | • | |
| Appendix A, Table A-3 | General Values for A ₁ and A ₂ . Would be revised to clarify the descriptive phrases for the contents and add a footnote to clarify the calculation of A ₁ for a group containing both alpha emitting radionuclides and beta or gamma emitting radionuclides when the groups are based on the total alpha activity and the total beta and gamma activity. | | • |

¹ The alternate tests allowed by the incorporation by reference are more stringent and costly to perform than the tests prescribed in 10CFR 71.75. Because they are alternative approaches and current practice is to use the tests prescribed in 10 CFR 71.75(c), it is estimated that there are no costs associated with this change.

² The alternate tests allowed by the incorporation by reference are more stringent and costly to perform than the tests prescribed in 10 CFR 71.75(b)(1) and (2). Because they are alternative approaches and current practice is to use the tests prescribed in 10 CFR 71.75, it is estimated that there are no costs associated with this change, with the exception of the alternate test allowed for specimens weighing less than 500 grams. The added flexibility for the test for specimens weighing less than 500 grams may have additional benefits and may be more likely to be used. The costs/benefits for this test have been estimated for this RA.

³ The changes to the preliminary determinations involve changes that would reflect that package marking and testing is done by certificate holders, rather than the user of the package. Licensees would be required to ensure that the preliminary determinations have been made. The changes do not change the preliminary determinations that are to be performed before the first use of the package, so it is estimated that there will be no costs associated with these changes, which also reflect current industry practice.

5. DECISION RATIONALE

The assessment of costs and benefits discussed previously leads the NRC to the conclusion that the proposed rule, if implemented, would improve regulatory efficiency and effectiveness for transportation of radioactive material, and would benefit industry with small changes to measures of public health and safety. There is a need to amend regulations to achieve compatibility with the IAEA's TS-R-1 safety standards. Finally, there is a benefit to amend the regulatory requirements that result in holders of a QA program approval having to submit all changes to their QA program description to the NRC for prior approval. Under the proposed rule, holders of a QA program approval would only need to submit to the NRC changes to their QA program description if the change would result in a reduction in the commitments that they have made to the NRC.

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 proposed by the DOT. These changes can be done through rulemaking with a one-time implementation cost to the NRC, Industry, and the Agreement States equal to about \$1.5 million followed by an annual operating cost savings of approximately \$63,000.

Alternative 3 would amend regulations as described in the proposed rule. These amendments would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency and to provide benefits to licensees and to the NRC and Agreement States with a small change to measures of impacts to public health and safety. The implementation cost would be equal to approximately \$2,284,000 followed by an annual savings to industry of an estimated \$112,000 (in 2012 dollars). The NRC has determined that Alternative 3 is superior to either of the other alternatives, and improves regulatory efficiency.

6. IMPLEMENTATION

The proposed rule is planned for publication in the *Federal Register* in November 2012. Following a public comment period and several months to review the public comments, the NRC staff will revise the proposed rule as appropriate and submit to the Commission in 2013 a proposed final rule.

7. REFERENCES

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- IAEA Safety Standards Series. IAEA SSR-6, 2012, "Regulations for the Safety Transport of Radioactive Material," IAEA, Vienna.
- IAEA Safety Standards Series. IAEA TS-R-1, Amended 2009, "Regulations for the Safe Transport of Radioactive Material," IAEA, Vienna.
- NRC, "RA Technical Evaluation Handbook, Final Report," NUREG/BR-0184, January 1997.
- U.S. Department of Labor, Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages.
- DOE, "A Resource Handbook on DOE Transportation Risk Assessment," DOE/EM/NTP/HB-01, July 2002.
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- U.S. Geological Survey, 2011, Mineral commodity summaries 2011: U.S. Geological Survey.

- L.D. Cunningham, "Columbium (Niobium) and Tantalum," Minerals Yearbook Volume 1. Metals and Minerals, U.S. Bureau of Mines, 1992, pp. 435-436.

Appendix 1: Input Assumptions and Line Item Results relating to Alt 2

| | Hours | \$ Per Hour | Total One-time Cost (2012) |
|---|--------|-------------|----------------------------|
| NRC effort to develop final rule and amend guidance | 2031 | 119 | \$241,689 |
| Agreement States' effort to develop final rule and amend guidance | 19,980 | 60.80 | \$1,214,784 |

- 37 Agreement States X 444 hours (.25) gives us the AS hours plus and additional 3,552 hours for the CRCPD efforts.

| Change | Truck Shipments/Year | Licensee Cost or Savings to Comply with Transportation Regulations (\$/truck shipment) | Annual Cost of Shipments (20121\$) |
|-----------|----------------------|--|------------------------------------|
| Table A-1 | | | |
| cf-252 | 5 | (500) | (2,500) |
| lr-192 | | | |
| kr-79 | 25 | (500) | (12,500) |
| kr-81 | 0 | 0 | 0 |
| mo-99 | 0 | 0 | 0 |
| Table A-2 | | | |
| kr-79 | 25 | (100) | (2,500) |
| kr-81 | 0 | 0 | 0 |
| Te-121m | 25 | (100) | (2,500) |
| Totals | | | (20,000) |

Detailed Quantitative Results relating to Licensee Costs/Savings for Alt 2

| 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 |
|------------------------|---|------------------|------------------|--------------------------------------|-------------------------|-------------------|----------------|----------------------|----------------------|
| ALTERNATIVE # 2 | | | | | | | | | |
| 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) | Would incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and would 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 | | | | | | -\$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 |

Appendix 2: Detailed Quantitative Results relating to Licensee and NRC Costs/Savings for Alt 3

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 |
|------------------------|---|------------------|------------------|--------------------|-------------------------|-------------------|------------------|----------------------|----------------------|
| ALTERNATIVE # 3 | | | | | | | | | |
| 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 would be revised to remove references to renewals of QA program approvals, which would 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 |
|------------|---|------------------|-------------------|------------------------|--------------------------|--------------------|---------------------|---------------------------|---------------------------|
| | RA rule prep Alternative 3 | | | | | \$0 | \$362,605 | \$362,605 | \$362,605 |
| 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 | -\$28,560 | \$0 | -\$243,623 | -\$200,593 |
| 71.106 (a) | Holders of a QA Program Approval would 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 | -\$8,330 | \$0 | -\$71,057 | -\$58,506 |
| 71.106(b) | Report to the NRC those changes that do not require prior NRC approval. | 125 | 1 | 125 | 1 | \$14,875 | \$0 | \$126,887 | \$104,476 |
| | | | | | | | Total One Time Cost | | |
| | | | | | | | \$367,365 | | |
| | | | | | | -\$22,015 | TOTAL | \$179,573 | \$212,741 |

DRAFT ENVIRONMENTAL ASSESSMENT AND FINDING OF
NO SIGNIFICANT IMPACT
FOR THE PROPOSED 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

November 2012

I. THE PROPOSED ACTION

The proposed action is to amend the U.S. Nuclear Regulatory Commission's (NRC) Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71 regulations. The proposed amendments would revise the requirements for the packaging and transportation of radioactive material.

1. Make the NRC regulations compatible with the 2009 edition of the International Atomic Energy Agency (IAEA) transportation standard, "Regulations for the Safe Transport of Radioactive Material" (TS-R-1),
2. Maintain consistency with changes in the U.S. Department of Transportation's (DOT) regulations, and
3. Make other changes.
 - a. Revise the requirements for shipping fissile material under a general license. The fissile material would be required to be homogeneously distributed and not form a lattice arrangement.
 - b. Revise quality assurance program regulations to (1) 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 (2) implement a change in practice where quality assurance program approvals would not expire.

II. THE NEED FOR THE PROPOSED ACTION

The IAEA is authorized to establish safety standards to protect public health and safety and to minimize the danger to life or property. The IAEA has developed international safety standards for the safe transport of radioactive material, TS-R-1. The IAEA safety standards are developed in consultation with the competent authorities of Member States — the U.S. is a Member State and the DOT is the U.S. competent authority before the IAEA for radioactive material transportation matters, so they reflect an international consensus on what is needed to provide for a high-level of safety. By providing a global framework for the consistent regulation of the transport of radioactive material, the international transportation standards facilitate international commerce and contributes to the safe conduct of international trade involving that material. By periodically revising its regulations to be compatible with the IAEA and DOT regulations, the NRC is able to remove inconsistencies between the national regulations and those of other countries that are based on the IAEA transportation standards that could impede international commerce.

The IAEA periodically reviews and revises its transportation standards to reflect knowledge gained in scientific and technical advances and accumulated experience. The NRC has a long-standing practice of harmonizing its packaging and transportation regulations with those of the DOT and the IAEA. On January 26, 2004 (69 FR 3698), the NRC published in the *Federal Register* a final revision to 10 CFR Part 71, “Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments.” That revision, in combination with a parallel revision of the hazardous materials transportation regulations of the

DOT, brought the U.S. domestic transport regulations into general accord with the 1996 edition of TS-R-1 (as amended in 2000). The DOT published its corresponding revision to Title 49 of the CFR on the same date (69 FR 3633). This rulemaking effort involves changing provisions in the NRC regulations at 10 CFR Part 71 to increase consistency and compatibility with the 2009 edition of TS-R-1 and changes being proposed by the DOT. In November 2012, the IAEA issued new standards for the safe transport of radioactive material and designated them as “Specific Safety Requirements Number SSR-6” (SSR-6). This rulemaking does not incorporate the 2012 IAEA changes, which will undergo a comprehensive review by the NRC staff to determine if additional changes to 10 CFR Part 71 are warranted. In addition to making the changes necessary to maintain consistency with the IAEA’s transportation standards and the DOT regulations, the NRC is proposing to revise 10 CFR Part 71 to streamline the regulatory oversight of quality assurance programs and to correct and clarify other requirements.

Consistent with the approach taken in the IAEA’s transportation standards, the NRC and DOT regulations include exemption values, which allow material that poses a slight radiological risk to be exempted from the transportation regulations. This allows material that would not typically be considered to be radioactive to be transported without the additional regulations required for radioactive material (i.e., it would not be required to be handled as hazardous material while being transported). Material that qualifies for the exemption from the regulations that apply to the transportation of radioactive material is not exempted from other regulatory controls, including the controls that apply to the disposal or release of radioactive material.

The current, radionuclide-specific exemption values replaced the activity concentration threshold of 70 Bq/g (0.002 μ Ci/g) that were used previously. Many natural materials and ores containing naturally occurring radionuclides qualified for the exemption when it was based on the activity concentration threshold of 70 Bq/g (0.002 μ Ci/g), but exceed the

radionuclide-specific exemption values. The IAEA recognized that applying the radionuclide-specific, activity concentration exemption values that it established in TS-R-1 to natural materials and ores might result in unnecessary regulation of these shipments. The IAEA established a broader exemption for these materials to avoid the unnecessary regulation of these materials during transport — comprising all operations and conditions associated with the movement of the radioactive material — which pose only a slight radiological risk. The IAEA exemption for natural materials and ores containing naturally occurring radionuclides allows the activity concentration of the material to be up to 10 times the values for the activity concentration for exempt material, if the material is not intended to be processed for the use of the naturally occurring radionuclides. The NRC and DOT regulations include this exemption for natural materials and ores.

In 2003, the IAEA changed the exemption for natural materials and ores to specifically include natural materials and ores that have been processed for purposes other than the extraction of the radionuclides. The NRC is proposing to change its requirements to allow natural materials and ores that have been processed to qualify for the exemption to be consistent with the IAEA exemption.

This proposed rulemaking is needed for the NRC to: (1) make changes in 10 CFR Part 71 to make the NRC regulations for the packaging and transportation of radioactive material compatible with the 2009 edition of the IAEA's transportation standards (TS-R-1), (2) maintain consistency with changes in the DOT regulations; and (3) make other changes to the requirements for the packaging and transportation of radioactive material.

III. ENVIRONMENTAL IMPACTS OF PROPOSED ACTION

The proposed action consists of a number of proposed changes to 10 CFR Part 71. Many of these proposed changes fall within the categorical exclusions listed in 10 CFR 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 table below shows those proposed changes that fall within the categorical exclusions and the categorical exclusion that is being applied to the change.

Table 1: Changes Qualifying for Categorical Exclusions

| Proposed Change | Alternative(s) |
|--|----------------|
| 10 CFR 51.22(c)(2) provides a categorical exclusion for amendments in 10 CFR Chapter I (including Part 71) that are corrective or of a minor or non-policy nature and do not substantially modify existing regulations. | |
| 10 CFR 71.0(d)(1). Revise to delete § 71.20 from the list of sections for which general licenses are issued without a required NRC package approval. This change is corrective in nature and does not substantially change the existing regulations, because § 71.20 has already expired. | 2, 3 |
| 10 CFR 71.17(c). Revise to clarify that the requirements in paragraph (c) are a responsibility of the general licensee and not a condition required to be satisfied to be granted the general license. General licensees would still be required to have (or maintain) a copy of the applicable certificate and related documents and to comply with the terms and conditions of the license, certificate, or other approval and the applicable requirements of subparts A, G, and H. No new requirements have been added. Therefore, this change is corrective and minor in nature and does not substantially modify the regulations. | 3 |
| 10 CFR 71.19. Redesignate paragraphs (b) through (e) and revise | 3 |

| | |
|--|------|
| redesignated paragraph (b)(2). Paragraph (a) has expired. Revise paragraph (b)(2) to delete the unnecessary phrase “[a]fter December 31, 2003,” because all future shipments would now occur after that date. These changes are corrective in nature and do not substantially change the existing regulations. | |
| 10 CFR 71.21 paragraph (a). Revise paragraph (a) to update the cross-reference to the applicable DOT requirement, which was relocated by the DOT in a recent rulemaking. This change is corrective in nature and does not substantially change the existing regulations. | 2, 3 |
| 10 CFR 71.21(d). Revise paragraph (d) to clarify that the requirement addresses the responsibility of the general licensee rather than a requirement to be granted a general license and to delete a sentence that exempts the general licensee from quality assurance requirements for design, construction, and fabrication activities that do not apply to a general licensee. General licensees would still be required to have (or maintain) a copy of the applicable certificate and related documents and to comply with the terms and conditions of the license, certificate, or other approval and the applicable requirements of subparts A, G, and H. No new requirements have been added. Therefore, these changes are corrective and minor in nature and do not substantially modify the regulations. | 3 |
| 10 CFR 71.75(b). Revise to correct the description of the billet and the lead sheet in (b)(2)(ii) and (b)(2)(iii). These changes are corrective in nature and do not substantially change the existing regulations. | 2, 3 |
| 10 CFR 71.85 paragraphs (a), (b), and (c). Revise by replacing “licensee” with “certificate holder” and add paragraph (d) to require the licensee to ensure that the preliminary determinations have been made. These changes are minor in nature and address who is responsible for making the preliminary determinations, so the changes do not substantially change the regulations. | 3 |
| 10 CFR 71.101(a). Revise to clarify the responsibilities of licensees and certificate holders to reflect the activities that licensees and certificate holders conduct. This change is minor in nature and does not substantially modify the existing regulations. | 3 |
| 10 CFR 71.103(a). Revise to remove a footnote, because subsequent changes made to the regulations that explicitly address the application of quality assurance requirements to certificate holders and applicants for a certificate of compliance have made the footnote unnecessary. This change is corrective in nature and does not substantially change the existing regulations. | 3 |
| Part 71, Appendix A, 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. These changes clarify the process of calculating values for A_1 and A_2 and make corrections. These changes are either corrective or of a minor nature that do not substantially modify the existing regulations. | 2, 3 |
| Part 71, Appendix A, Table A-1. Revise the A_1 entry for californium-252 (Cf- | 2, 3 |

| | |
|---|------|
| <p>252) to the IAEA value in TS-R-1. The IAEA has revised the A_1 value for Cf-252 to the value that currently applies to domestic transportation. This change is minor, corrective in nature, and does not substantially modify existing regulations, because the A_1 value for domestic transportation would not be changed. Revise the entry for iridium-192 (Ir-192) to relocate footnote c to the columns that provide the A_1 values. Revise the entry for krypton-81 (Kr-81) to reflect the addition of krypton-79 (Kr-79) to the table. Revise the entry for molybdenum-99 (Mo-99) to update the lettering of the footnote. Delete footnote h and redesignate footnote i as footnote h. Revise footnote a to identify that the A_1 and/or A_2 values that include contributions from daughter radionuclides with half-lives of less than 10 days. These changes are minor, corrective in nature, and do not substantially change the existing regulations.</p> | |
| <p>Part 71, Appendix A, Table A-2. Revise the entry for krypton-81 (Kr-81) to reflect that it is no longer the first entry for the isotopes of krypton. Revise footnote b to remove the chains for the parent radionuclides cerium-134 (Ce-134), radon-220 (Rn-220), thorium-226 (Th-226), and uranium-240 (U-240) and add a chain for silver-108m (Ag-108m). These changes are minor and corrective in nature and do not substantially change the existing regulations.</p> | 2, 3 |
| <p>Part 71, Appendix A, Table A-3. Revise the entries for column 1, "Contents," and add footnote a to indicate 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. These changes are minor and corrective in nature and do not substantially change the existing regulations, because the changes provide additional clarity that is intended to improve compliance with the regulations, but do not change the values or the material to which the values apply.</p> | 2, 3 |

| | |
|--|-------------|
| <p>10 CFR 51.22(c)(3) provides a categorical exclusion for amendments in 10 CFR Chapter I (including Part 71) which relate to: (i) 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; (ii) recordkeeping requirements; (iii) reporting requirements; (iv) education, training, experience, qualification, or other employment suitability requirements; or (v) actions on petitions for rulemaking related to these amendments.</p> | |
| <p>10 CFR 71.6 paragraph (b). Revise to remove an expired section from the list of information collections and add § 71.106 to the list of information collections. These changes pertain to information collection (reporting and recordkeeping); the removal of the expired section from the list of information collections is also corrective in nature and does not substantially modify the regulations.</p> | <p>2, 3</p> |
| <p>10 CFR 71.31(b). Revise to correct a reference to another section. This change pertains to the procedures for filing an application for a license or other form of permission. This change is also corrective in nature and does not substantially modify the regulations.</p> | <p>3</p> |
| <p>10 CFR 71.38. Retitle the section. Revise paragraphs (a), (b), and (c) to remove references to quality assurance program approvals, because the approvals would no longer require renewal. This change pertains to the procedures for filing a renewal application for a license or other form of permission.</p> | <p>3</p> |
| <p>10 CFR 71.91(a). Revise to correct a reference. This change pertains to recordkeeping requirements. This change is also corrective in nature and does not substantially modify the regulations.</p> | <p>3</p> |
| <p>10 CFR 71.101(c). Revise to separate the requirements for obtaining approval of a quality assurance program that apply to licensees from those that apply to certificate holders. This change relates to the procedures for filing for a form of permission. This change is also minor in nature and does not significantly modify the regulations, because licensees will not be conducting the fabrication, testing, or modification of the package.</p> | <p>3</p> |
| <p>10 CFR 71.106. Add the section. This section adds requirements that pertain to the process for making changes to approved quality assurance programs by revising the process for obtaining NRC approval to make changes to an approved quality assurance program. These changes relate to the procedures for filing and reviewing applications for a form of permission. The categorical exclusion also applies to any quality assurance records that would be created in response to the proposed amendments to § 71.106; because amendments are proposed for § 71.135, the proposed amendments to § 71.135 are addressed separately, below.</p> | <p>3</p> |
| <p>10 CFR 71.135. Revise to include changes made to an approved quality assurance program as a quality assurance record. This change relates to recordkeeping requirements.</p> | <p>3</p> |

The proposed action, which corresponds to the changes identified as alternative 3 in the Table 1, also consists of a number of proposed 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 where they are described in more detail and their environmental impacts are discussed.

Table 2: Proposed Changes Evaluated in the Environmental Assessment

| Section | Subject | Proposed Changes | Alternative(s) | Analysis |
|-----------------------|--|---|----------------|---------------------|
| 71.4 | Definitions | Add definition of "contamination". 10 CFR Part 71 does not currently include this definition. It is being added as part of the effort to harmonize with TS-R-1, so adding this definition is considered under Alternatives 2 and 3. | 2, 3 | See Section III.A. |
| 71.4 | Definitions | Revise definition of "Criticality Safety Index (CSI)". | 2, 3 | See Section III. A. |
| 71.4 | Definitions | Revise definition of "Low Specific Activity (LSA) material". | 2, 3 | See Section III.A. |
| 71.4 | Definitions | Revise definition of "special form radioactive material". | 2, 3 | See Section III.A. |
| 71.4 | Definitions | Revise definition of "uranium – natural, depleted, enriched". | 2, 3 | See Section III. A. |
| 71.14 | Exemption for low-level materials | Revise paragraph (a), add paragraph (a)(3). | 2, 3 | See Section III.B. |
| 71.15 | Exemption from classification as fissile material | Revise paragraph (d). | 3 | See Section III.C. |
| 71.70 | Incorporation by reference | Add a section that consolidates incorporation by reference language. | 2, 3 | See Section III.D. |
| 71.75 | Qualification of special form radioactive material | Revise paragraphs (a)(5) and (d). | 2, 3 | 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. | 2, 3 | 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. | 2, 3 | See Section III.E. |

A. Revised Definitions

Description of the Change: The definition for “contamination” would be added to § 71.4; the definition is consistent with the definition in the DOT transportation regulations at 49 CFR Part 173 and IAEA TS-R-1. The definition of “Criticality Safety Index (CSI)” would be revised to be consistent with the definition in the DOT 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” would be revised to be consistent with the definition in the DOT regulations at 49 CFR Part 173 and IAEA TS-R-1 by making the description of LSA-I 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” would be revised to allow special form radioactive material that was successfully tested using the current requirements of § 71.75(d) to continue to qualify as special form radioactive material. The definition of “uranium — natural, depleted, enriched”, would be revised by adding “(which may be chemically separated)” to the portion of the definition that describes natural uranium. This portion of the definition would become “[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 (Alternatives 2 and 3): The proposed changes to the definitions of “Criticality Safety Index (CSI)” and “uranium — natural, depleted, enriched” provide clarifications. Because 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 “natural uranium” does not alter the distributions of uranium isotopes used to describe the “natural uranium” and 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 “natural uranium” is used.

The proposed change in the definition of “Low Specific Activity (LSA) material” would correct the definition of LSA-I material. Currently, the NRC definition of LSA-I material includes the word “not” which makes the NRC definition inconsistent with the DOT definition of LSA material (which does not include the word “not”). Removal of the word “not” would make the NRC definition for LSA-I 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 would 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., below.

The changes to the definition of special form radioactive material would allow material already tested to continue to qualify as special form radioactive material. Because the proposed changes allow the continued use of special form radioactive material that has been qualified using the current tests and do not change the requirements applicable to this qualified material, there would be 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., below.

Environmental Impacts for No Change (No Action Alternative): For the same reasons as

discussed above, not making the proposed changes to the definitions of CSI, “uranium — natural, depleted, enriched,” and LSA-I would not result in environmental impacts.

The environmental impacts from not changing the definition of contamination are evaluated in Section III.B., below.

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., below.

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 would be changed to indicate that such natural material or ore could be in either its natural state or have been processed. The exemption would also be changed to specifically allow non-radioactive solid objects with “contamination” to be transported without being handled as hazardous material.

Environmental Impacts from the Change (Alternatives 2 and 3): 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 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 would be 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 proposed change would allow some additional material to qualify for the exemption with activity concentrations 10 times the activity concentration for exempt material, because it explicitly allows material that has been processed to qualify for the exemption.

Although material that may qualify for the exemption under the proposed changes would be 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 involve radiation exposure. Although 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 would be far below the public dose limits and consider both normal conditions and accident conditions (i.e., an individual effective dose of 10 μ Sv/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, 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 would be 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 ingestion, inhalation, and spreading hazards, whereas fixed contamination would only contribute to increased exposures, but would be limited to a low exposure. Contamination below the values in the definition would only contribute to insignificant exposures through inhalation, ingestion or external exposure and the derived values are conservative with respect to transportation and would not cause environmental

contamination. So, this change would have 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 presents 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 would still ensure that the doses for both normal and accident conditions would remain well below the public dose limits for normal and accident conditions.

The exemption, which also appears in the DOT regulations, already covers many types of material from mining and minerals processing, building materials, and other natural materials. Therefore, large quantities of material are currently transported under the current exemption, do not involve activities licensed by the NRC, and would not be subject to the NRC 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. The regulations that apply to shipments of radioactive material would not apply to material qualifying for the exemption. Material that is categorized 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, and within the variability of the value of the commodities, relative to the value of the material most likely to qualify under this expanded exemption, the proposed 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 $\mu\text{Sv}/\text{year}$ (1 mrem/year) for the shipment of tantalum raw materials; (3) individual loads of some materials, depending on their composition (such as higher activities of radium), could lead to higher doses; and (4) doses to members of the public were at least an order of magnitude lower than for workers. The preliminary results of the Coordinated Research Program were generally consistent with allowing increased activity concentrations for naturally occurring material and ore containing naturally occurring radionuclides. Allowing activity concentration values of 10 times the exemption value would still limit doses (from either single or multiple sources) so that they do not reach unacceptable levels and would be 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 would be small and not significant. Removing the regulatory controls for transporting this material would 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 would not significantly increase the amount of material being transported. The preliminary results of the Coordinated Research Program indicate that radiological exposures would remain small and well below unacceptable

levels and public dose limits for both normal conditions and accident conditions. Environmental impacts associated from accidental releases would 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 would be small.

Environmental Impacts for No Change (No Action Alternative): 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 would be far below the public dose limits and consider both normal conditions and accident conditions (i.e., an individual effective dose of 10 μ Sv/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, 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 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 proposed changes are not made. Without the changes, the material would not qualify for the exemption and would continue to be transported as Class 7 (radioactive) material. Class 7 (radioactive) material may, depending on the routing and mode of transport, be subject to fees and restrictions that may change. To avoid fees or other restrictions, the material that would only qualify for the exemption if the changes were made may be transported over longer routes than would similar material is able to qualify for the current low-level material exemption. As a result, not changing the low-level material exemption would result in small impacts from the longer transportation routes. Because the requirements that apply to this material do not significantly affect the radiological exposures, the radiological

impacts would be small.

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 a General License

Description of the Change: The NRC is proposing to revise § 71.15(d) criteria that, if satisfied, will exempt the material from being classified as fissile material and from the fissile material package standards in §§ 71.55 and 71.59. The NRC would further restrict the exemption for uranium enriched with uranium-235 to a maximum of 1 percent by weight to fissile material that is homogeneously distributed and does not form a lattice-like arrangement, where fissile material is concentrated and separated by non-fissile material in a regular, repeating pattern.

Environmental Impacts of the Change (Alternative 3): The proposed change would ensure that material containing uranium enriched in uranium-235 to a maximum of 1 percent by weight and qualifying for the fissile material exemption under § 71.15(d) would be subcritical and criticality would not be a potential hazard for this material during transportation. The fissile material that would no longer qualify for the fissile material exemption would be shipped using

the fissile material package standards of §§ 71.55 and 71.59 or, if the requirements for a general license to ship fissile material are met, a Type A package. The requirements for a general license to ship fissile material include (1) the package contents contain no more than a Type A quantity of radioactive material and (2) the package contents contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium. The requirements at §§ 71.55 and 71.59 require that packages and arrays of packages remain subcritical. The restrictions for a general license to ship fissile material also provide a margin of safety with respect to criticality. This change would reduce the likelihood of criticality associated with transporting this material; consequently, the environmental impacts associated with this material becoming critical during transport would be reduced. 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. Reducing the likelihood of criticality further would decrease 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 (Alternative 2 and No Action Alternative): The restrictions for a general license to ship fissile material provide a margin of safety with respect to 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 not change. Also, and no other changes, such as uranium enriched in uranium-235 to a maximum of 1 per cent by weight that is not homogeneously distributed or forms a lattice arrangement having to be shipped under a general license rather than under the fissile material exemption

would be required. Therefore, there would be no change in the environmental impacts from the fissile material exemption change.

D. Qualification of Special Form Radioactive Material

Description of the Change: The NRC is proposing to allow 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 would make the NRC requirements consistent with TS-R-1 and the proposed DOT requirements. The NRC is proposing to update 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 proposing to update 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 would make 10 CFR Part 71 consistent with the DOT requirements at 49 CFR Part 173, which incorporated by reference ISO 9978:1992(E) in 2004. The NRC is proposing to continue 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 (Alternatives 2 and 3): 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 proposed changes would

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 may pass 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 proposed 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. The impacts of not making this change would be small, because special form radioactive material is often tested using the tests specified in TS-R-1, which are included in 10 CFR Part 71 and are less stringent than the tests in the consensus standards.

E. Changes to Appendix A, Determination of A₁ and A₂

Description of the Change: The NRC is proposing to add an entry for krypton-79 (Kr-79) in Table A-1, "A₁ and A₂ 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 proposing to discontinue using the A₂ value for californium-252 (Cf-252) in footnote h to Table A-1, "A₁ and A₂ Values for Radionuclides," in Part 71, Appendix A, that applies for domestic transportation. The A₂ value for Cf-252 in Table A-1 would be used for domestic transportation. The NRC is proposing to change the total consignment activity limit for exempt consignment for tellurium-121m (Te-121m) from 1x10⁵ Bq (2.7x10⁻⁶ Ci) to 1x10⁶ Bq (2.7x10⁻⁵ Ci) in Table A-2 in Part 71, Appendix A.

Environmental Impacts of the Change (Alternatives 2 and 3): Krypton-79 (Kr-79) is not listed in Table A-1 in Part 71, Appendix A, and the values from Table A-3, "General Values for A₁ and A₂," in Part 71, Appendix A, are used to determine the A₁ and A₂ values of Kr-79. The A₂ value for Cf-252 would change from 1x10⁻³ TBq (2.7x10⁻² Ci) to 3x10⁻³ TBq (8.1x10⁻² Ci).

The A₁ and A₂ values are used for determining which type of package must be used for the transportation of radioactive material. The A₁ values are the maximum amount of special form material allowed in a Type A package. The A₂ values are the maximum activity of normal form radioactive material allowed in a Type A package. The A₁ and A₂ 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 A₁ and A₂ have been adopted in 10 CFR Part 71 and are specified in Appendix A.

The A₁ and A₂ 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 A₁ 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 are irradiated and the committed dose equivalent to these organs or tissues. The values of committed effective dose in the IAEA 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 proposed for Table A-1 are larger than the values derived from 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 if the generic values in Table A-3 were to be used, 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 current values. The A_2 value for Cf-252 that would apply to domestic transportation would increase, which would allow higher activities of normal form

Cf-252 to be shipped in a Type A package than would be allowed in if the A_2 value in footnote h to Table A-1 were to be used. The values are derived using the “Q [quantity]-system” (see 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 an 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 Basic Safety Standards (i.e., an individual effective dose of $10 \mu\text{Sv}/\text{year}$ ($1 \text{ mrem}/\text{year}$) 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 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 would 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 would 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 different than 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 you have to meet both sets of requirements. This generally makes it more expensive to import or export radioactive material. Making no change to the values would have small environmental impacts. The generic values in Table A-3 that are used for Kr-79 are smaller than the proposed A_1 and A_2 values and the A_2 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 could be shipped in a Type A package than would be allowed by the proposed change. Under the no action alternative, the maximum quantity of material available for release from a package would be proportionally smaller than the maximum quantity available for release from a package under the proposed action. As discussed above, the releases from the 2 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. Therefore, the environmental impacts from not making this change would be small and would be proportionally smaller under the no action alternative than under the proposed action.

Environmental Impacts Associated with the Proposed Action (Alternative 3)

The environmental impacts associated with the proposed amendments 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 amendments 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 proposed changes would affect the alternate tests used to qualify special form radioactive material; however, the proposed amendments would not result in significant changes to the currently available tests or the number of tests performed.

The proposed changes 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 amendments would not significantly change the amount of transportation of radioactive material. 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.

IV. ALTERNATIVES TO THE PROPOSED ACTION

The following alternatives were considered.

Alternative 1: The No-Action Alternative

The NRC would take no action. This would leave in place the current regulations. The environmental impacts associated with the proposed amendments 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.

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 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 1 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 change currently available 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. The impacts of not making this change would be small, because special form radioactive material is often tested using the tests specified in TS-R-1, which are included in 10 CFR Part 71 and are less stringent than the tests in the consensus standards.

The proposed amendments would not significantly affect the amount of transportation of radioactive material transported domestically. If the NRC and the DOT do not make changes that will maintain consistency between their regulations, it would result in increased regulatory uncertainty as licensees would need to determine what is actually allowed and resolve

inconsistencies between the NRC and DOT requirements. This would 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 would be more difficult and costly for some materials. Licensees would need to meet both agencies requirements which adds to the cost and places 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 regulations and DOT 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

The NRC would conduct a rulemaking to make the NRC regulations compatible with the 2009 edition of the IAEA international transportation standards (TS-R-1) and the changes to DOT requirements. The NRC would not make any NRC-initiated, substantive changes. The environmental impacts associated with the proposed amendments 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 amendments 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 additional changes that qualify for a categorical exclusion, because they fall within a category of actions that neither individually nor cumulatively would have significant impact on the human environment. This alternative does not include adding additional restrictions to the fissile material exemption for uranium enriched in uranium-235 to a maximum of 1 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.

The proposed amendments would not result in significant changes to currently available tests or the number of tests performed. The proposed amendments would not significantly change the amount of transportation of radioactive material. 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 needed changes to 10 CFR Part 71 – such as the change to the fissile exemption criteria, which is necessary for the continued safe transport of uranium enriched in uranium-235 to a maximum of 1 percent by weight that qualifies for the exemption from being classified as fissile material by increasing the margin of safety for shipments under the fissile material exemption – that would not have a significant environmental impact.

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 DOT during the preparation of the proposed rule and the preparation of this draft Environmental Assessment, consistent with the memorandum of understanding between the NRC and the DOT (44 FR 38690; July 2, 1979). The NRC sent a copy of the draft Environmental Assessment and the proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment.

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 issuance of the proposed 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 proposed amendments would amend the requirements for packaging and transportation of radioactive material. The amendments would make changes to harmonize the NRC regulations with the 2009 edition of the IAEA's transport regulations (TS-R-1)) and the DOT regulations for the transportation of radioactive material; expand the exemption for the domestic shipping of natural materials and ores containing naturally occurring radionuclides; reintroduce a prohibition on the heterogeneously distributed fissile material from being shipped under a general license; 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 proposed 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. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

IN RESPONSE, PLEASE
REFER TO: M031120A

November 20, 2003

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 11:30 A.M.,
THURSDAY, NOVEMBER 20, 2003, COMMISSIONERS'
CONFERENCE ROOM, ONE WHITE FLINT NORTH,
ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-03-0141 - Final Rule to Revise 10 CFR Part 71 to Be Compatible with IAEA
Transportation Safety Standards [TS-R-1] and Make Other NRC-Initiated Changes

The Commission approved a final rule which amends 10 CFR Part 71 to conform NRC's transportation regulations with the IAEA Transportation Safety Standards and ensures consistency with the Department of Transportation's Hazardous Materials Regulations. The Commission approved the publication and implementation of this final rule subject to the comments and changes noted in the attachment.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO)

(SECY Suspense:

12/22/03)

The staff should continue to keep the Commission informed of future changes to the IAEA's Transportation Safety Standards, while they are still under discussion, in order to provide the Commission an early opportunity to provide input to the staff on these changes.

The staff should pursue an additional rulemaking with DOT to remove the apparent double standard related to shipments of natural ores or NORM and allow a similar exemption for material with equivalent risk. This rulemaking allows transportation exemptions of up to ten times the exempt values in the rule for shipments of ore or NORM intended for mineral production or disposal. However, it would not exempt shipments of ore or NORM intended for isotope processing that is part of the nuclear fuel cycle. In order to be consistent with our overall risk-informed approach to regulations, staff should advocate change proposals in future revisions of the IAEA transportation regulations that would apply the 10 times exemption to all NORM materials consistently regardless of their intended use.

The staff should come to the Commission one month after the date of the SRM on this SECY paper with a plan for resolution of the new concerns recently identified by the staff related to the change authority for dual use canisters and propose a final regulatory solution pathway to the Commission. This pathway should not include initiation of new rulemaking on this issue. Since

this issue has already been discussed in a proposed rule and comments collected, the staff can move forward with resolving the comments and issuing a final rule in a short time frame.

The staff should continue to work with industries that are not regulated by the NRC (such as the zircon sand and other mineral extraction industries) to limit the impact on them during the implementation of this rule.

Attachment:
As stated

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
EDO
OGC
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

Changes to the Final Rule in SECY-03-0141

Prior to publication, the Federal Register notice (FRN) should be revised to incorporate the following changes:

1. The responses under “Adequacy of NRC Regulations and Rulemaking Process” should be revised to more carefully distinguish between the meaning and significance of “**biological** effects” and “**health** effects.”
2. The FRN should not include statements that are not evidence-based, i.e., can not be supported by data, peer reviewed journals, etc., e.g., on page 26 the statement “Recently, concern has been expressed that long-term exposure to low levels of radiation may be more dangerous than short-term exposures to high levels” should be deleted based on the following statement that ““However, there is no epidemiology data, published in peer reviewed journals, to support this concern.”
3. References for significant scientific conclusions that have appeared in peer-reviewed scientific journals should be provided, e.g., the statement “No birth defects or genetic disorders among the children born to atomic bomb survivors from Hiroshima and Nagasaki have been observed at low doses of radiation (<25 rad)” on page 26.
4. The FRN should be carefully screened for phrases and terms that have no clear meaning, e.g., what is meant by “**mildly** radioactive materials” on page 24 and “any **undue** increase in exposure” on page 28.
5. The FRN should be carefully reviewed to ensure that it contains the most up-to-date information, e.g., on page 37 the response to a comment on which countries have already adopted the proposed IAEA guidelines is based on a September 2002 survey.
6. The FRN should be reviewed to make sure that it does not leave the reader searching for information, e.g., on page 89 it states that “while some revised A_1 and A_2 values are higher and some are lower, the potential dose following an accident is the same as with the previous A_1 and A_2 values” but the reader is not provided with the dose upon which the values are based.
7. Prior to the effective date of the regulation, staff should approach DOT to determine whether the 1967 designs are adequate for domestic shipping from a public health and safety perspective. If the conclusions of this meeting are that the 1967 designs should still be phased out, staff should actively engage with industry to ensure there are adequate staff resources available to review new transportation package certifications so that transportation of radioactive sources will not be significantly impacted at the end of the transition period. In particular, the staff should monitor the impact of this rulemaking on small businesses during the transition period. The staff should keep the Commission informed of any significant adverse impacts identified during this transition period.
8. The staff should work with OGC on the specific wording of the Federal Register Notice related to allowing holders of transportation certificates for dual use canisters (i.e., canisters which can be used for transportation and storage) to make limited changes without NRC approval. It should indicate that staff will work with appropriate stake

holders to resolve new concerns recently identified by the staff and propose a final regulatory solution to the Commission.

9. The FRN and associated documents should be revised to more clearly communicate what the term “double containment” means in the context of this regulation.
10. On page 13, next to last paragraph, revise the last line to read ‘ ... ~~support safe shipments~~ **are robust and protective of the public during transportation of spent fuel. Therefore even with an increase in the number of shipments, these shipments can be made safely** in large numbers to a’
11. On page 16, last paragraph, revise line 4 to read ‘ ... Study (PPS), and **full-scale** ~~real~~ cask tests’
12. On page 17 next to last paragraph, revise lines 4 and 5 to read ‘ ... Therefore, no **changes were made to this rulemaking** ~~NRC action is necessary~~. The NRC’
13. On page 21, the response does not address the comment and should be revised.
14. On page 25, the response should add a statement explaining the recently issued DOT regulations concerning security plans and driver identification cards.
15. On page 27, last paragraph, the last sentence is unclear and should be revised.
16. On page 28, the 1st paragraph is unclear and needs to be revised.