

**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](mailto:Carol.Gallagher@nrc.gov).
- **E-mail comments to:** [Rulemaking.Comments@nrc.gov](mailto: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.

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## 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](mailto: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](mailto: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](mailto: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](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,<sup>1</sup> 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

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<sup>1</sup> 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., D<sub>2</sub>O or heavy water), and carbon (graphite) (C) should be maintained. The ORNL recommended that the moderator criteria restricting the mass of Be, C, or D<sub>2</sub>O 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  $k_{\text{eff}}$  of 0.95 when optimally moderated by water. For the material to become critical,<sup>2</sup> the  $k_{\text{eff}}$  would need to be greater than or equal to 1.0. However, the quantity and geometric arrangement of this material exceeded a  $k_{\text{eff}}$  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  $k_{\text{eff}}$  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  $k_{\text{eff}}$  greater than 0.95,  $k_{\text{eff}}$  is very insensitive to changes in geometry and quantity; consequently, significantly larger quantities of material would be required to get  $k_{\text{eff}}$  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

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<sup>2</sup> 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  $0.4 \text{ Bq/cm}^2$  ( $1 \times 10^{-5} \text{ } \mu\text{Ci/cm}^2$ ) for beta and gamma emitters and low toxicity alpha emitters, or  $0.04 \text{ Bq/cm}^2$  ( $1 \times 10^{-6} \text{ } \mu\text{Ci/cm}^2$ ) 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<sub>1</sub> and A<sub>2</sub> 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<sub>1</sub> and A<sub>2</sub> values for Cf-252; revise footnote a to include the list of parent radionuclides whose A<sub>1</sub> and A<sub>2</sub> 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<sub>1</sub> and A<sub>2</sub> values are used for determining what type of package must be used for the transportation of radioactive material. The A<sub>1</sub> values are the maximum amount of special form material allowed in a Type A package. The A<sub>2</sub> values are the maximum activity of “other than special form” material allowed in a Type A package. A<sub>1</sub> and A<sub>2</sub> 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<sub>1</sub> and A<sub>2</sub> 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<sub>1</sub> and A<sub>2</sub> 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  $1 \times 10^5$  Bq ( $2.7 \times 10^{-6}$  Ci) to  $1 \times 10^6$  Bq ( $2.7 \times 10^{-5}$  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  $9 \times 10^{-5}$  TBq ( $2.4 \times 10^{-3}$  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.<sup>3</sup> 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

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<sup>3</sup> 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  $\mu\text{m}$  [(5x10<sup>-3</sup> 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 ( $k_{\text{eff}}$ ) 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  $k_{\text{eff}}$  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  $k_{\text{eff}}$  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  $k_{\text{eff}}$  to exceed 0.95. In the case of uranium enriched to a maximum of 1 percent by weight,  $k_{\text{eff}}$  is not sensitive to changes in mass,



so a significant amount of additional mass would be required to increase the  $k_{\text{eff}}$  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,  $k_{\text{eff}}$  is very sensitive to moderator conditions. If the moderator conditions are not optimal,  $k_{\text{eff}}$  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  $k_{\text{eff}}$  and includes a minimum margin of subcriticality. At a  $k_{\text{eff}}$  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  $5.0 \times 10^{-2}$  TBq to  $1.0 \times 10^{-1}$  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  $4.2 \times 10^4$  TBq/g

( $1.1 \times 10^6$  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  $1.0 \times 10^3$  Bq/g ( $2.7 \times 10^{-8}$  Ci/g) and the value for the activity limit for exempt consignment would be  $1.0 \times 10^5$  Bq ( $2.7 \times 10^{-6}$  Ci). The activity limit for exempt consignment for Te-121m would be revised from  $1 \times 10^5$  Bq ( $2.7 \times 10^{-6}$  Ci) to  $1 \times 10^6$  Bq ( $2.7 \times 10^{-5}$  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 <sup>1</sup>
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).

			§ 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><b>**Note:</b> 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><b>**Note:</b> 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><b>**Note:</b> 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><b>**Note:</b> 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

71.101(g)	Revised Compatibility Category Note	requirements Quality assurance requirements	C <b>**Note:</b> 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 <b>**Note:</b> 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**. <b>**Note:</b> § 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 <b>**Note:</b> § 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**. <b>**Note:</b> § 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 <b>**Note:</b> § 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).

			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 <b>**Note:</b> 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 <sub>1</sub> and A <sub>2</sub>	[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 <sub>1</sub> and A <sub>2</sub> 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]

Table A-3	column 1, "Contents," and add footnote a.	A <sub>1</sub> and A <sub>2</sub>		
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<sup>1</sup> 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](mailto: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/cm<sup>2</sup> for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm<sup>2</sup> 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 43<sup>rd</sup> Street, 4<sup>th</sup> floor, New York, NY 10036, 212-642-4900, <http://www.ansi.org>, or [info@ansi.org](mailto: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/in<sup>2</sup>) 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 A<sub>1</sub> AND A<sub>2</sub>**

\* \* \* \* \*

IV. \* \* \*

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

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



where B(i) is the activity of radionuclide i in special form, and A<sub>1</sub>(i) is the A<sub>1</sub> value for radionuclide i.

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

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

where B(i) is the activity of radionuclide i in normal form, and A<sub>2</sub>(i) is the A<sub>2</sub> value for radionuclide i.

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

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

Where B(i) is the activity of radionuclide i as special form radioactive material, A<sub>1</sub>(i) is the A<sub>1</sub> value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A<sub>2</sub>(j) is the A<sub>2</sub> value for radionuclide j.

d. Alternatively, the A<sub>1</sub> 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 A<sub>1</sub> 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 <sub>1</sub> (TBq)	A <sub>1</sub> (Ci) <sup>b</sup>	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci) <sup>b</sup>	Specific activity	
						(TBq/g)	(Ci/g)
*	*	*		*	*	*	*
Cf-252		1.0x10 <sup>-1</sup>	2.7	3.0x10 <sup>-3</sup>	8.1x10 <sup>-2</sup>	2.0x10 <sup>1</sup>	5.4x10 <sup>2</sup>
*	*	*		*	*	*	*
Ir-192		1.0 <sup>c</sup>	2.7x10 <sup>1c</sup>	6.0x10 <sup>-1</sup>	1.6x10 <sup>1</sup>	3.4x10 <sup>2</sup>	9.2x10 <sup>3</sup>
*	*	*		*	*	*	*
Kr-79	Krypton (36)	4.0	1.1x10 <sup>2</sup>	2.0	5.4x10 <sup>1</sup>	4.2x10 <sup>4</sup>	1.1x10 <sup>6</sup>
Kr-81		4.0x10 <sup>1</sup>	1.1x10 <sup>3</sup>	4.0x10 <sup>1</sup>	1.1x10 <sup>3</sup>	7.8x10 <sup>-4</sup>	2.1x10 <sup>-2</sup>
*	*	*		*	*	*	*
Mo-99 (a)(h)		1.0	2.7x10 <sup>1</sup>	6.0x10 <sup>-1</sup>	1.6x10 <sup>1</sup>	1.8x10 <sup>4</sup>	4.8x10 <sup>5</sup>
*	*	*		*	*	*	*

<sup>a</sup> A<sub>1</sub> and/or A<sub>2</sub> 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

\* \* \* \* \*

<sup>c</sup> 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.

\* \* \* \* \*

<sup>h</sup>  $A_2 = 0.74$  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)	$1.0 \times 10^3$	$2.7 \times 10^{-8}$	$1.0 \times 10^5$	$2.7 \times 10^{-6}$
Kr-81		$1.0 \times 10^4$	$2.7 \times 10^{-7}$	$1.0 \times 10^7$	$2.7 \times 10^{-4}$
*	*	*	**	*	*
Te-121m		$1.0 \times 10^2$	$2.7 \times 10^{-9}$	$1.0 \times 10^6$	$2.7 \times 10^{-5}$
*	*	*	**	*	*

\* \* \* \* \*

<sup>b</sup> 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 <sub>1</sub>		A <sub>2</sub>		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 <sup>a</sup>	2x10 <sup>-1</sup>	5.4x10 <sup>0</sup>	9x10 <sup>-5</sup>	2.4x10 <sup>-3</sup>	1x10 <sup>-1</sup>	2.7x10 <sup>-12</sup>	1x10 <sup>3</sup>	2.7x10 <sup>-8</sup>
Neutron emitting nuclides are known to be present or no relevant data are available	1x10 <sup>-3</sup>	2.7x10 <sup>-2</sup>	9x10 <sup>-5</sup>	2.4x10 <sup>-3</sup>	1x10 <sup>-1</sup>	2.7x10 <sup>-12</sup>	1x10 <sup>3</sup>	2.7x10 <sup>-8</sup>

<sup>a</sup> If beta or gamma emitting nuclides are known to be present, the A<sub>1</sub> 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.