Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

[NRC–2016–0179]

RIN 3150–AJ85

Harmonization of Transportation Safety Requirements With IAEA Standards

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation, is proposing to amend its regulations for the packaging and transportation of radioactive material. The NRC has historically revised its transportation safety regulations to ensure harmonization with the International Atomic Energy Agency standards. These changes are necessary to maintain a consistent regulatory framework with the U.S. Department of Transportation for the domestic packaging and transportation of radioactive material and to ensure general accord with International Atomic Energy Agency standards. Concurrently, the NRC is issuing for public comment Draft Regulatory Guide DG–7011, which would become Revision 3 to Regulatory Guide 7.9, ''Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material.''

DATES: Submit comments by November 28, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2016–0179. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individual or individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Firth, 301–415–6628, email: *James.Firth@nrc.gov;* or Bernard White, 301–415–6577, email: *Bernard.White@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0179 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2016–0179.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2016–0179 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. 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 submission. 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 into ADAMS.

II. Background

On June 12, 2015, the NRC, in consultation with the U.S. Department of Transportation (DOT), published a final rule that amended the NRC's regulations for the packaging and transportation of radioactive material (80 FR 33988; June 12, 2015). These amendments made conforming changes to the NRC's regulations based on the standards of the International Atomic Energy Agency (IAEA). That final rule, in combination with a DOT final rule (79 FR 40589; July 11, 2014) amending title 49 of the *Code of Federal Regulations* (49 CFR), brought U.S. regulations into general accord with the 2009 Edition of the IAEA's ''Regulations for the Safe Transport of Radioactive Material'' (TS–R–1). The IAEA has since updated its standards for the transport of radioactive material in ''Regulations for the Safe Transport of Radioactive Material,'' Specific Safety Requirements No. 6 (SSR–6) (2012 and 2018 Editions).

The IAEA develops international safety standards for the safe transport of radioactive material. The IAEA safety standards 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, IAEA safety standards facilitate international commerce and contribute to the safe conduct of international trade involving radioactive material. By periodically revising its regulations to be compatible with IAEA standards and DOT regulations, the NRC can remove inconsistencies that could impede international commerce.

The roles of the DOT and the NRC in the coregulation of the transportation of radioactive materials are documented in a Memorandum of Understanding (44 FR 38690; July 2, 1979). Because of the coregulation of the transportation of radioactive materials in the United States, the NRC and the DOT have historically coordinated to harmonize their respective regulations with the IAEA revisions through the rulemaking process. In the NRC's previous 10 CFR part 71 harmonization rulemaking, published in the **Federal Register** on June 12, 2015, the Commission stated that the NRC will consider any necessary changes related to SSR–6 in a future rulemaking after consulting with DOT.

The NRC engaged with the DOT in the development of this proposed rule to identify and evaluate gaps between 10 CFR part 71 regulations and the updated IAEA standards in SSR–6, 2018 Edition. This proposed rule would close those gaps where warranted. Harmonizing NRC regulations with the 2018 Edition of SSR–6 includes changes made in the 2012 Edition of SSR–6 that have been carried forward to the 2018 Edition. The DOT is undertaking a similar initiative to harmonize its regulations in 49 CFR parts 107 and 171–180 with the 2018 Edition of SSR–6.

The NRC reviewed the 2018 Edition of SSR–6 and identified 10 regulatory issues for harmonization with the IAEA and another 4 NRC-initiated changes to 10 CFR part 71 to be evaluated during the rulemaking development process. Fourteen of these issues were documented in the ''Issues Paper on Potential Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements'' (issues paper). The issues paper, public meeting, and request for comment were published in the **Federal Register** (81 FR 83171; November 21, 2016). The NRC held a public meeting on December 5–6, 2016, to discuss the issues paper, and the DOT participated in that public meeting. A summary of the public meeting, including the attendance list, was issued on December 14, 2016. After the public meeting, the NRC received 49 comment submissions on the issues paper identified comments that are pertinent to this proposed rule, and considered these comments in the development of a draft regulatory basis. In addition to the 14 issues documented in the paper, the NRC identified other potential changes to the regulations, including clarifications to ensure compatibility with the DOT and changes to the compatibility categories for Agreement State regulations. These potential changes were grouped under a new issue that was designated as Issue 15 in the draft regulatory basis. All 15 issues are described in Section III of this document.

On April 12, 2019, the NRC published the draft regulatory basis for this proposed rule in the **Federal Register** and requested public comments (84 FR 14898; April 12, 2019). In the regulatory basis, the NRC evaluated four alternative actions for each issue. These were: Alternative 1—take no action and maintain the status quo; Alternative 2—issue generic communications and regulatory guidance; Alternative 3—issue license-specific conditions and exemptions; and Alternative 4–initiate a rulemaking action to revise 10 CFR part 71. The alternatives were evaluated based on their viability to resolve the regulatory issues of concern and estimates of their costs and potential benefits. The NRC determined that the rulemaking action, Alternative 4, for Issues 1 (in part), 2, and 4–15, in combination with the no-action alternative, Alternative 1, for Issue 3, was the NRC-recommended action because it represented the most effective and least-costly option. Alternatives 2 and 3 would not address all of the regulatory issues or would result in higher costs to the NRC and industry.

The NRC also held a public meeting on April 30, 2019, to discuss the draft regulatory basis and answer questions. The NRC received seven public comment submissions on the draft regulatory basis—three with general comments on the rulemaking and four with comments on specific issues—as well as comments that were considered outside the scope of this proposed rule. All three general comments were supportive of the harmonization effort with IAEA SSR–6. The NRC did not receive any comments on Issues 2, 6, and 14. The NRC received comments supportive of the proposal for Issues 4b, 11, 12, 13 and 15, along with comments supportive of other issues which also recommended modifications to the NRC's proposed changes. One comment on Issue 5 proposed the NRC add a definition of ''radiation level'' to 10 CFR part 71, which the NRC included in this proposed rule.

One comment on Issue 1 stated that the fissile exemption mass limits in 10 CFR part 71 should match those in SSR–6, paragraph 417, to avoid confusion for international shipments from the United States. The NRC has determined that its regulations for fissile exemption mass limits should differ from the IAEA's requirements to provide flexibility for shippers. Specifically, the NRC requirements in this proposed rule would adopt a 3.5-gram limit from SSR–6, paragraph 417(c), but without the associated consignment limit found in paragraph 570(c); they also would adopt a higher mass limit than SSR–6, paragraph 417(e). Several existing fissile exemptions under § 71.15 do not have corresponding exceptions under SSR–6, paragraph 417; if the NRC made 10 CFR part 71 fissile exemptions identical to the fissile exceptions in SSR–6, paragraph 417, fissile material licensees would lose the benefit of these exemptions. Also, the NRC is not pursuing the competent authority-approved exception in SSR–6,

paragraph 417(f). The NRC has determined that the current fissile exemptions under § 71.15 provide flexibility for shipping low masses or concentrations of fissile materials, and licensees can submit a specific exemption request under § 71.12 for fissile materials that do not meet the fissile exemption criteria in § 71.15.

The NRC received comments on Issues 4 and 8 which suggested that the NRC ''grandfather'' packages from having to meet the revised requirements. The NRC is proposing to ''grandfather'' older packages as discussed in Issue 10, ''Transitional Arrangements.''

Comments on Issue 4 on the proposed insolation requirements stated that these requirements would present challenges to certificate holders, including cost to certificate holders to evaluate the new conditions; changing the units without revising the corresponding values may result in decreasing margins or exceeding thermal limits; and the insolation values are referenced in other documents, which may have an impact to the thermal evaluations for storage systems certified under 10 CFR part 72. While the NRC agrees there will be costs with evaluating the new insolation requirements, the NRC estimates that the cost for existing certificates to show compliance with the revised insolation will be small, since the increased insolation load would be approximately 3 percent. In addition, harmonizing NRC requirements with those of IAEA will ensure that packages approved by the NRC would also be acceptable in other countries where they might be used for international transport. The NRC made no changes as a result of this comment. The NRC recognizes that all packages age over time and that aging effects should be considered for all packages, not just for dual-purpose packages.

The NRC received comments on Issue 9 opposing the addition of an aging management program to 10 CFR part 71. The commenters stated that, if such a program were added, the program should be limited to packages other than dual-purpose spent nuclear fuel packages/canisters. The NRC is not proposing to impose a requirement for an aging management plan. The proposed rule includes requirements that aging effects are evaluated in the application for approval and that the application for approval include a maintenance program. Another comment on Issue 9 supported evaluating aging effects but only for dual-purpose spent fuel packages, excluding packages that are not kept in long-term storage prior to transport.

One comment on Issue 10 supported phasing out older packages as proposed in transitional arrangements but suggested a phase-out period longer than 4 years. The NRC agreed and is proposing an 8-year phase out of older packages. As part of the NRC's 2004 amendment to 10 CFR part 71 (69 FR 3697; January 26, 2004), certain transportation packages, those compatible with the 1967 edition of Safety Series No. 6, became unauthorized for use under the 10 CFR part 71 general license after October 1, 2008. The NRC received requests to extend the phase-out date beyond the initial 4-year period to allow sufficient time to design, obtain approval for, and fabricate new packages. Given this experience, in this proposed rule, the NRC has selected a phase-out period of 8 years to give certificate holders sufficient time to conduct these activities, if needed. The NRC estimates that it could take 2 to 4 years for design of a new package and preparation of an application, 1 to 2 years for package approval, and 1 to 2 years for package fabrication, depending on the package's complexity. Another comment on Issue 10 on transitional arrangements stated that the NRC should not phase out packages with a ''–96'' in the package identification number and that the proposed phase out of packages did not consider the cost impact for designing new packages. The NRC is not proposing to phase out packages with a ''–96'' in the proposed rule, but rather proposing to phase out packages that do not have either a ''–85'' or a ''–96'' in the package identification number (*i.e.,* packages approved before April 1, 1996). The NRC included the cost of designing a new package in the regulatory analysis for the proposed rule.

The NRC received one comment on Issue 12 on the proposed quality assurance program (QAP) changes, stating that the proposed change would be duplicative with 10 CFR part 50 QAP requirements. The NRC disagrees with this comment because if a 10 CFR part 50 licensee uses its 10 CFR part 50 QAP for 10 CFR part 71 activities, the QAP reporting requirements in 10 CFR part 50 would be controlling and 10 CFR part 71 QAP reporting requirements would not apply. Also, the NRC notes that many users of 10 CFR part 71 do not have 10 CFR part 50 licenses, and the 10 CFR part 71 QAP change provisions would not be duplicative for them.

The NRC received a comment on Issue 15 on the advance notification requirements in § 71.97, stating that there is no actual provision requiring advance notification for spent fuel shipments. The requirements in § 71.97 currently contain reporting requirements that are duplicative with those in 10 CFR part 73, and the NRC is proposing to delete the duplicative language.

Because none of the comments would result in significant changes to the draft regulatory basis, the NRC considered these comments in preparing this proposed rule and did not issue a final regulatory basis.

III. Discussion

A. Action the NRC is Proposing To Take

The NRC is proposing to amend its regulations to harmonize them with the IAEA international transportation standard No. SSR–6 (2018 Edition). These revisions would be coordinated with DOT and its hazardous materials regulations to maintain a consistent framework for the domestic transportation and packaging of radioactive material.

This proposed rule also would revise 10 CFR part 71 to include administrative, editorial, or clarifying changes, including changes to certain Agreement State compatibility category designations that are further discussed in Section XV, ''Compatibility of Agreement State Regulations,'' of this document.

B. Applicability of the Proposed Action

This action would affect (1) NRC licensees authorized by a Commission-issued specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, or transports the material outside of the site of usage as specified in the NRC license, or transports that material on public highways; (2) holders of, and applicants for, a certificate of compliance (CoC) under 10 CFR part 71; and (3) holders of a 10 CFR part 71 QAP approval. This action also would change requirements that are a matter of compatibility with the Agreement States. Therefore, the Agreement States would need to update their regulations, as appropriate, at which time those licensees in Agreement States would need to meet the compatible Agreement State regulations.

C. Discussion of Issues

The NRC is proposing to revise 10 CFR part 71 as described in the 15 issues listed in this document and summarized in the following table (note that the issue numbers described in Section III.C of this document are consistent with those described in the regulatory basis):

Issue	IAEA harmonization	DOT harmonization	Other changes	No action
1	X			
2				X
3				X
4.1	X			
4.2	X			
5	X			
6	X	X		
7	X	X		
8	X			
9	X			
10	X	X		
11	X	X		
12			X	
13			X	
14			X	
15.1			X	
15.2			X	
15.3	X	X		
15.4			X	
15.5			X	

Issue 1. Revision of Fissile Exemptions

The fissile material exemptions in § 71.15 and the fissile material general licenses in §§ 71.22 and 71.23 allow licensees to ship low-risk fissile material (*e.g.,* small quantities or low concentrations) without meeting the fissile material packaging requirements and criticality safety assessments, as specified in §§ 71.55 and 71.59, and without obtaining prior NRC approval. For these low-risk fissile material shipments, the fissile material exemptions and general licenses provide reasonable assurance that criticality safety is afforded under normal conditions of transport and hypothetical accident conditions. In 2012, IAEA modified the fissile exception provisions in SSR–6, paragraph 417, to include three new per-package mass limit options, with associated mass limits on the consignment and/or conveyance.

The NRC proposes to incorporate two additional fissile exemptions under § 71.15. This proposed rule would adopt the exception in SSR–6, paragraph 417(c), without the associated consignment limit of IAEA SSR–6, paragraph 570(c). This proposed rule would also adopt the exception in SSR–6, paragraph 417(e), with its associated exclusive use restriction in paragraph 570(e), but with a higher mass limit.

Since the amount of fissile material allowed by SSR–6, paragraph 417(c), is similar to the existing exemption in § 71.15(a), in terms of reactivity, the NRC determined that the consignment limit of IAEA SSR–6, paragraph 570(c), is not necessary. Consignment limits, as provided in 570(c), do not prevent the accumulation of packages on a transport conveyance, as there is no limit to the number of consignments that may be present on a single conveyance. Additionally, the number of these packages does not need to be limited by regulation because reaching the amount required to approach criticality on a single conveyance is not credible.

The NRC has determined that a mass value higher than that contained in IAEA SSR–6, paragraph 417(e), is justified, given the conservatism inherent in the exclusive use restriction of the SSR–6 provision, and in basing the mass limit on plutonium-239 (^{239}Pu), which would have to be shipped in a Type B package. The NRC proposes a limit of 140 grams of fissile material on a conveyance shipped under exclusive use, as another exemption under § 71.15. This limit is based on one fifth of a minimum critical mass of uranium-235 (^{235}U) (as defined in American National Standards Institute/American Nuclear Society [ANSI/ANS] 8.1–2014 (Reaffirmed 2018), ''Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors'') under optimum conditions. This mass represents a conservative limit for fissile material, since five times this amount would remain subcritical under any condition. Additionally, the limit provides safety equivalent to packages approved under 10 CFR part 71 and could provide more flexibility for shipping individual contaminated items or small quantities of fissile material. The NRC considers ^{235}U for this limit rather than ^{239}Pu, as any amount of ^{239}Pu over 0.435 grams is considered Type B, which would have to be packaged to withstand both normal and hypothetical accident conditions of transport. Although the NRC proposed value is different from the IAEA SSR–6, paragraph 417(e), value, the NRC determined that the higher value is technically justified and will be appropriate for NRC licensees who ship specific waste streams (*e.g.,* decommissioning waste), and that there will be little international shipment from the United States of this type of material. Licensees who ship material internationally must comply with DOT requirements for the use of international standards in title 49, ''Transportation,'' of the CFR.

Additionally, the NRC is not proposing to adopt the ''packaged or unpackaged'' language in the fissile exception provision of IAEA SSR–6, paragraph 417(e). The 140-gram limit, as with other fissile exemption provisions in § 71.15, only relieves the consignor from having to ship in a ''Fissile'' package, evaluated per the requirements of §§ 71.55 and 71.59. This material is still subject to all other radioactive materials transportation requirements in 10 CFR part 71 and in 49 CFR part 173 and should be packaged accordingly. The NRC is proposing to make a minor change to § 71.15(d) for clarity and to maintain consistent language throughout § 71.15.

Issue 2. Revision of Reduced External Pressure Test for Normal Conditions of Transport

The regulation at § 71.71(c)(3) requires Type AF and Type B package designs to be able to withstand a reduction in external pressure to 25 kilopascals (kPa) (3.6 psia) under normal conditions of transport. For a Type A package (as defined in SSR–6, paragraphs 231 and 429; 10 CFR 71.4, ''Definitions''; or 49 CFR 173.403, ''Definitions''), IAEA SSR–6, paragraph

645, states that ''[t]he containment system shall retain its radioactive contents under a reduction of ambient pressure to 60 kPa.'' This requirement also applies to Type B(U) and Type B(M) packages, in accordance with SSR–6, paragraphs 652 and 667, respectively. Additionally, IAEA SSR–6, paragraph 621, indicates packages containing radioactive material to be transported by air shall be capable of withstanding, without loss or dispersal of the radioactive contents from the containment system, an internal pressure that produces a pressure differential of not less than maximum normal operating pressure plus 95 kPa (13.8 psi).

In a final rule published by the DOT (79 FR 40589; July 11, 2014), the DOT harmonized its regulations in 49 CFR chapter I to the 2009 Edition of IAEA TS–R–1. In that final rule, the DOT explained that a Type A package must be designed to ensure the package can retain its contents under the reduction of ambient pressure. That ambient pressure value, found at 49 CFR 173.412(f), was changed from 25 kPa (3.6 psia) to 60 kPa (8.7 psia).

The NRC considered whether it should change the reduced external pressure test requirement in § 71.71(c)(3) to harmonize with the IAEA transport standards and to be consistent with the DOT regulations for design requirements for Type A packages. The NRC assessed the potential impacts of the change in the external pressure value from 25 kPa (3.6 psia) to 60 kPa (8.7 psia) and the additional air transport requirements from SSR–6, paragraph 621. The current NRC reduced external pressure test requirement, 25 kPa (3.6 psia), equates to an altitude of about 35,000 feet (10,668 meters) above sea level, which is an appropriate altitude for air transport of packages. Since cargo planes use pressurized cargo holds during air transport, this external pressure value also represents the ambient pressure on a package should the cargo hold depressurize. Whereas the 60 kPa (8.7 psia) value equates to an altitude of about 14,040 feet (4,279 meters) above sea level. Thus, while the 60 kPa (8.7 psia) external pressure value equates well with the highest paved road in the United States (14,130 feet (4,307 meters)) and with the elevation of the highest operating freight railroad in the United States (La Veta Pass at 9,242 feet (2,817 meters)), it would not support air transport conditions, as cargo planes operate at higher altitudes. When comparing the current 25 kPa (3.6 psia) value with the proposed 60 kPa (8.7 psia) value, and the associated altitudes, the NRC determined that no change to § 71.71(c)(3) is needed, and the 25 kPa (3.6 psia) value should be retained.

The NRC also considered adding the air transport requirements from SSR–6, paragraph 621. However, other than specific air transport requirements at § 71.55(f), ''General requirements for fissile material packages'' and § 71.88, ''Air transport of plutonium,'' 10 CFR part 71 does not contain ''mode-specific'' regulations. Because the existing reduced external pressure test value covers air transport conditions as discussed above, and because of the robustness of Type AF and Type B packages, as compared to Type A packages, the NRC finds it unnecessary to add the mode-specific air transport requirements from SSR–6, paragraph 621, into 10 CFR part 71.

Based on the above considerations and assessments, the NRC has decided not to pursue any changes to § 71.71(c)(3). As a result, no further discussion or analysis is presented in this proposed rule on the reduced external pressure test for normal conditions of transport.

Issue 3. Inclusion of Type C Package Standards

In the 2004 final rule, the NRC did not adopt the regulations for Type C packages contained in IAEA TS–R–1. The NRC did not adopt them because 1) §§ 71.64 and 71.74 for plutonium air transportation contain more rigorous packaging standards, 2) the NRC perceived no need (current or anticipated) for such packages, and 3) if a need arose for import or export, it could be accomplished through the DOT regulations.

In the request for comment on the issues paper, the NRC asked stakeholders whether there was a need for domestic transport of Type C packages. No NRC licensees expressed a need for domestic transport of Type C packages. Therefore, the NRC has decided not to pursue further changes to Type C package standards as contemplated in the regulatory basis document. As a result, no further discussion or analysis is presented in this proposed rule on that issue.

Issue 4. Revision of Insolation Requirements for Package Evaluations

During transport, a package is subjected to heating by the sun, called insolation. The effect of insolation is an increase in the package temperature. The NRC is proposing to change the unit of measure for the values of insolation used for the heat test for normal conditions of transport in § 71.71(c)(1), and to add insolation to the initial conditions for the tests for hypothetical accident conditions in § 71.73(b).

Issue 4.1. Revision of Units for Insolation for Normal Conditions of Transport

The units for insolation in 10 CFR part 71 are gram calories per square centimeter (g cal/cm^2). When the IAEA published Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material, 1985 Edition,'' it revised the units used for insolation for normal conditions of transport from a hybrid of English and metric units (g cal/cm^2) to metric units (watts per square meter (W/m^2)). When the IAEA changed the units, it chose to keep the same numerical values, thus increasing the evaluated solar heat load on a package by approximately 3 percent. The IAEA did not provide a technical rationale for this change; however, the NRC observes that retaining the existing numerical quantities maintains simple (round) values in the regulations that result in a small change in solar heat load.

The NRC previously harmonized its regulations with the 1985 Edition of Safety Series No. 6 (60 FR 50248; September 28, 1995). That final rule neither discussed nor proposed changing the units on the heat test for normal conditions of transport in § 71.71(c)(1). Consequently, the current units for insolation in 10 CFR part 71 are ''g cal/cm^2.'' This is inconsistent with IAEA standards in the 2018 Edition of SSR–6. As a result, NRC package approvals are evaluated for less insolation than that prescribed by IAEA standards and evaluated for approval by foreign competent authorities.

The NRC is proposing to revise the units of insolation for the heat test for normal conditions of transport in § 71.71(c)(1) to match the units used in the 2018 Edition of SSR–6 to ensure that NRC requirements for insolation are consistent with the IAEA standard. Consistent with Issue 10, ''Transitional Arrangements,'' the NRC would not expect a certificate holder to evaluate the higher solar heat load unless it requests a revision of its certificate to show compliance with the revised transportation regulations in 10 CFR part 71. Additionally, given the small increase in insolation due to the revised units, the NRC expects that certificate holders will be able to show compliance with the package approval standards in subpart E, ''Package Approval Standards,'' to 10 CFR part 71.

Issue 4.2. Inclusion of Insolation for Hypothetical Accident Conditions

In Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990),'' paragraph 628 stated, ''With respect to the initial conditions for the thermal test, the demonstration of compliance shall be based upon the assumption that the package is in equilibrium at an ambient temperature of 38 °C. The effects of solar radiation may be neglected prior to and during the tests, but must be taken into account in the subsequent evaluation of the package response.''

The thermal test, previously in paragraph 628, was moved to paragraph 728 in the 1996 Edition of TS–R–1 and revised to state, ''The specimen shall be in thermal equilibrium under conditions of an ambient temperature of 38 °C, subject to the solar insolation conditions specified in Table XI and subject to the design maximum rate of internal heat generation within the package from the radioactive contents.''

When the NRC revised its regulations in 2004 to harmonize with the 1996 IAEA standards (69 FR 3697; January 26, 2004), the NRC did not revise the initial conditions of the fire test listed in § 71.73(b) to require evaluation of insolation as an initial condition.

Since a fire can occur on a hot, sunny day, and to be consistent with IAEA standards, the NRC is proposing to revise the initial conditions in § 71.73(b) to require insolation as an initial condition for all the tests for hypothetical accident conditions. Consistent with Issue 10, ''Transitional Arrangements,'' the NRC would expect a certificate holder to evaluate the revised initial conditions in § 71.73 if it wants to revise its certificate to show compliance with the revised transportation regulations in 10 CFR part 71.

Issue 5. Inclusion of Definition for Radiation Level

The term ''radiation level'' was first introduced in the IAEA transport standards in Safety Series No. 6, 1973 Edition, and it was defined in terms of ''dose-equivalent rate'' as ''the corresponding radiation dose-equivalent rate expressed in millirem per hour.'' External radiation standards were defined in terms of radiation levels in each subsequent edition of the IAEA's transport standards, including the 2012 Edition of SSR–6. In the 2018 Edition of SSR–6, the IAEA replaced the term ''radiation level'' with the term ''dose rate'' and defined the dose rate to be the dose-equivalent per unit time. Because the current regulations in 10 CFR part 71 use the term ''radiation level,'' the NRC is concerned that using a different term from the IAEA to define external radiation standards could create some confusion with respect to international shipments.

Additionally, NRC regulations in 10 CFR part 20, ''Standards for Protection Against Radiation,'' include a definition for ''dose equivalent'' in § 20.1003 that means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

The NRC considered replacing the term ''radiation level'' used throughout 10 CFR part 71 with ''dose equivalent rate.'' However, this change would result in cost impacts to licensees to change documentation and training programs with no safety benefit. Therefore, in order to minimize the burden to licensees, the NRC is proposing to add a definition to § 71.4 that clarifies that ''radiation level'' means ''dose equivalent rate,'' which enables the NRC to continue using ''radiation level'' throughout 10 CFR part 71. The NRC is not expecting any licensee to change its documentation to account for this new definition.

Issue 6. Deletion of Low Specific Activity-III Leaching Test

The definition for ''Low Specific Activity (LSA) material'' in § 71.4 includes three categories of material: LSA–I, LSA–II, and LSA–III. Radioactive material, low specific activity category III (*i.e.,* LSA–III) includes solids, excluding powders, that meet the requirements in § 71.77, ''Qualification of LSA–III material'' and which have an estimated average specific activity limit that does not exceed 2×10^{-3} times the A_2 value per gram (A_2/g). The qualification tests in § 71.77 include a leaching test with immersion of the specimen material for 7 days. The IAEA eliminated the LSA–III leaching test in SSR–6, 2018 Edition, from paragraphs 409, 601, and 701. Consequently, the NRC is proposing corresponding revisions to §§ 71.4, 71.77, and 71.100, ''Criminal penalties,'' to remove the leaching test and its references.

In April 2015, an international working group meeting was conducted to discuss issues related to LSA–II and LSA–III material, with special attention on the need for the LSA–III leaching test. The need for the leaching test was questioned because the working group determined that the test has no bearing on the inhalation risk of exposure to material during transport. The inhalation risk is used to determine the average specific activity limits for both LSA–II and LSA–III material, which are $10^{-4}A_2$/g and $2 \times 10^{-3}A_2$/g, respectively. Related investigations dating back to 2003 revealed that the amount of released radioactive material leading to an inhalation dose under the mechanical tests for normal conditions of transport greatly depend on the physical form of the LSA material. The primary difference between LSA–II and LSA–III materials is that LSA–III is limited to solid material, excluding powders. Due to the solid nature of the LSA–III material, the amount of airborne radioactivity released during the mechanical tests for normal conditions of transport leading to an inhalation dose is at least a factor of 100 lower for LSA–III solids than for LSA–II solids in powder form. This much lower airborne release for LSA–III material due to its non-readily dispersible form outweighs the difference in average specific activity limit, which is 20 times greater for LSA–III compared to LSA–II material in powder form. Because of the non-dispersible form of the LSA–III material, the working group determined that there was no need to take credit from a leaching test to justify this allowable 20-fold increase in average specific activity between LSA–III and LSA–II material.

The NRC recognizes the working group's information, and is recommending harmonization with SSR–6, 2018 Edition, and removal of the leaching test from 10 CFR part 71. The NRC agrees that requiring the LSA–III leaching test does not increase the safety of the material during transport. Further, the test does not decrease the inhalation pathway exposure when compared to LSA–II material in powder form, and therefore should be removed from 10 CFR part 71. The NRC considered the information provided by the LSA–II and LSA–III working groups and comments received on this issue during the comment period on the NRC's issues paper. Additionally, the NRC considers that removal of the leaching test also would reduce regulatory burden for shippers, while still maintaining reasonable assurance of safety for transport of LSA–III material.

The NRC is proposing to remove the leaching test in § 71.77 and make conforming changes to §§ 71.4 and 71.100, which both reference § 71.77.

Issue 7. Inclusion of New Definition for Surface Contaminated Object

As more nuclear facilities begin decommissioning activities, there will be an increase in the number of shipments of radioactive materials from

these facilities. Decommissioning activities can include transporting large radioactive objects (*e.g.,* steam generators, coolant pumps, and pressurizers). Under current NRC regulations, shipment of such large, nonstandard packages that do not meet the existing definition of surface contaminated objects (*i.e.,* either SCO–I or SCO–II, as defined in § 71.4) could be addressed through a special package authorization under § 71.41(d). However, such an authorization may take significant time. The NRC proposes to add a regulatory definition for SCO–III to include these types of objects, allowing a shipper to more appropriately categorize the item it is planning to transport. The NRC anticipates an increase in efficiency for both the NRC and licensees when the SCO–III definition is included in 10 CFR part 71 when compared to the special package authorization review needed under § 71.41(d). Harmonization with SSR–6, 2018 Edition, would add the new SCO–III category and the associated definition.

In the 2004 final rule (69 FR 3697; January 26, 2004), the NRC determined that special package authorizations were necessary because there were no regulatory provisions in 10 CFR part 71 concerning large, nonstandard packages considered for transportation. Therefore, the NRC added paragraph (d) to § 71.41. Since that time, the NRC has gained experience with the safety aspects of shipping these types of large, non-standard packages. For example, in 2006, the LaCrosse reactor vessel was the first shipment in which a package was approved under § 71.41(d). In addition, a special package authorization was issued for the West Valley Melter Package from the West Valley Demonstration Project. In the future, a licensee shipping large radioactive objects that have been determined to meet the definition of SCO–III would not need NRC review and approval for a special package authorization.

Both the NRC and DOT intend to add a definition for SCO–III. The NRC is coordinating with the DOT to align its definition with the DOT's, since the DOT is the lead agency for review and evaluation of both LSA and SCO material.

Issue 8. Revision of Uranium Hexafluoride Package Requirements

In the 2004 final rule (69 FR 3697; January 26, 2004), the NRC harmonized its regulations with the 1996 Edition of IAEA TS–R–1. In that final rule, the NRC added a new provision, § 71.55(g), to provide a specific exception for certain uranium hexafluoride (UF_6) packages from the requirements of § 71.55(b). The exception allows UF_6 packages to be evaluated for criticality safety without considering inleakage of water into the containment system, provided certain conditions are met, including that the uranium is enriched to not more than 5 weight percent in ^{235}U. To use this exception, the applicant must demonstrate, among other things, that, following the tests for hypothetical accident conditions in § 71.73, there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight. ''Leaktight'' is defined in ANSI N14.5–2014, ''American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment,'' as ''[t]he degree of package containment that, in a practical sense, precludes any significant release of radioactive materials. This degree of containment is achieved by demonstration of a leakage rate less than or equal to 1×10^{-7} ref·cm^3/s, of air at an upstream pressure of 1 atmosphere (atm) absolute (abs), and a downstream pressure of 0.01 atm abs or less.''

The NRC provided the specific exception: (1) to be consistent with the worldwide practice and limits established in national and international standards (ANSI N14.1–2012, ''Nuclear Materials—Uranium Hexafluoride—Packagings for Transport,'' and International Organization for Standardization 7195, ''Packaging of Uranium Hexafluoride (UF_6) for Transport'') and DOT regulations (49 CFR 173.417(b)(5)); (2) because of the history of safe shipment; and (3) because of the essential need to transport the commodity. In that final rule, the NRC codified its long-standing practice to not consider water inleakage into UF_6 packages as long as the documentation of the results of the tests for hypothetical accident conditions tests at § 71.73 show that the cylinder valve was not affected.

In SSR–6, 2018 Edition, the IAEA added the same standard for the plug as was added in the 1996 Edition of TS–R–1 for the valve to ensure that the entire cylinder remains leak tight. The revised paragraph 680(b)(i), SSR–6, 2018 Edition, states: ''Packages where, following the tests prescribed in para. 685(b), there is no physical contact between the valve or the plug and any other component of the packaging other than at its original point of attachment and where, in addition, following the test prescribed in para. 728, the valve and the plug remain leaktight.''

The 30-inch UF_6 cylinder, the most commonly used cylinder to transport large quantities of enriched UF_6 for the fuel fabrication industry, has two penetrations: one for the valve at the top to fill the cylinder and one for the drain plug at the bottom used during maintenance. In order to ensure criticality safety, both the plug and the valve must remain leak tight after the tests for hypothetical accident conditions to prevent ingress of water into the cylinder. While this may be a new requirement in transportation regulations, during package approval, the NRC has always verified that the entire 30B cylinder remained leak tight after the tests for hypothetical accident conditions.

The NRC is proposing to revise § 71.55(g)(1) to require that there is no contact between the cylinder plug and any other part of the packaging, other than at its original attachment point and that the cylinder plug remains leak tight, as NRC requires for the cylinder valve.

Issue 9. Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program

The NRC regulations do not explicitly require that a package application include an evaluation of aging mechanisms and a maintenance program. Rather, applicants include an evaluation of aging effects on package components to ensure there is no significant degradation in accordance with § 71.43(d). The NRC regulations at § 71.43(d) require that packages be made of materials and construction that assure that there will be no significant chemical, galvanic, or other reaction (including effects of irradiation from the package contents) among the packaging components, among package contents, or between the packaging components and the package contents, including possible reaction resulting from inleakage of water, to the maximum credible extent.

For those components where aging is detrimental to package performance, applicants provide a description of the maintenance program, including periodic testing to evaluate the components' efficacy and/or a replacement or repair schedule, to mitigate those detrimental effects. The NRC requires that licensees and CoC holders follow the maintenance program, which is provided in the application for approval, as a condition of approval in the CoC. Additionally, NRC regulations at § 71.87(b) require that, prior to each shipment, the licensee ensures that the package is in unimpaired physical condition except

for superficial defects such as marks or dents. Meeting this regulation, along with the scheduled periodic tests and replacement/repair in the maintenance program, should identify package deterioration prior to age-related degradation becoming a safety issue during transport.

In paragraph 613A, SSR–6, 2018 Edition, the IAEA added that package design evaluations must consider aging mechanisms. In paragraph 809, SSR–6, 2018 Edition, the IAEA added that the application for package approval must contain a maintenance program. Because an evaluation of aging effects and a description of the maintenance program are not specifically required by 10 CFR part 71, the NRC is proposing to revise § 71.43(d) to specifically include the evaluation of the effects of aging, and add a new provision to subpart D, ''Application for Package Approval,'' to include a description of the maintenance program in an application for package approval, to better align with these standards in SSR–6, 2018 Edition.

Issue 10. Revision of Transitional Arrangements

Historically, IAEA standards and DOT and NRC regulations have included transitional arrangements when the regulations have undergone revision. The purpose is to minimize the costs and impacts of implementing changes in the regulations, since package designs and special form sources that are compliant with the existing regulations do not become unsafe when the regulations are revised (unless a significant safety issue is corrected in the revision).

Typically, the transitional arrangements include provisions that allow for (1) continued use of existing package designs and packagings already fabricated; and completion of packagings in the process of being fabricated, although some restrictions on fabrication of packagings approved to earlier editions of the regulations may be imposed; (2) restriction on modifications to package designs without the need to demonstrate full compliance with the revised regulations; (3) changes in packaging identification numbers; and (4) changes to the fabrication and use of special form sources approved to earlier versions of the regulations.

The NRC CoCs include a package identification number which identifies the NRC regulations and the corresponding version of IAEA standards to which the package was approved. For example, packages with a ''–85'' in the package identification number were approved to NRC regulations compatible with the provisions of the 1985 or 1985 (as amended 1990) Editions of Safety Series No. 6. NRC packages with a ''–96'' in the package identification number were approved to NRC regulations compatible with the 1996 Edition of TS–R–1.

The IAEA updated its transitional arrangements in paragraphs 819–823, SSR–6, 2018 Edition, for packages that have a ''–85'' or ''–96'' in their package identification number. However, it does not include transitional arrangements for package designs approved under the IAEA's 1973 Edition of Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Materials.'' The NRC previously harmonized its requirements with the 1973 Edition; corresponding packages are those for which the CoC does not have a year designation in the package identification number. By not including transitional arrangements on these packages, the IAEA standards effectively phase out the use of these packages approved under the 1973 Edition of Safety Series No. 6.

The IAEA's SSR–6, 2018 Edition, also prohibits, after December 31, 2028, the fabrication of new packagings that have not been shown to meet SSR–6, 2018 Edition standards. This means that package designs approved to earlier versions of IAEA standards (*i.e.,* NRC-approved packages for which the CoC has a ''–96'' in its package identification number), could not be used unless fabrication is completed before January 1, 2029. Note that IAEA standards and NRC regulations already prohibit the use of packages that have ''–85'' in their package identification number on the CoC if their fabrication was not completed by December 31, 2006.

The IAEA's SSR–6, 2018 Edition, also phases out certain special form radioactive material. The NRC regulations contain a definition of, and the tests for, special form radioactive material. Special form radioactive material is either a non-dispersible solid or sealed in a capsule so that the dispersibility, and therefore the radiological hazard, of the radioactive material is diminished. In order to be designated as special form, the radioactive material must be evaluated using the tests and acceptance criteria in § 71.75.

Paragraph 823 of SSR–6, 2018 Edition, does not include provisions for use of special form radioactive material approved under 1973 Edition of Safety Series No. 6. In SSR–6, 2018 Edition, special form radioactive material that was shown to meet the provisions of the 1985 through 2012 Editions of IAEA standards may continue to be used, with some additional restrictions on approval and fabrication. The IAEA's SSR–6, 2018 Edition, prohibits fabrication of special form radioactive material that received unilateral approval under the 1985 Edition of Safety Series No. 6 or 1985 (as Amended 1990) Edition of Safety Series No. 6. Also, after December 31, 2025, IAEA standards prohibit new fabrication of special form radioactive material sources to a design that had received unilateral approval under the 1996 Edition; 1996 Edition (Revised); 1996 (as Amended 2003) Edition of TS–R–1; TS–R–1, 2005 Edition; TS–R–1, 2009 Edition; and SSR–6, 2012 Edition.

Finally, in paragraphs 832–833, SSR–6, 2018 Edition, the IAEA revised the package identification number in the CoC to delete the year designation (*i.e.,* ''–85'' or ''–96'') for those package designs that are approved to SSR–6, 2018 Edition.

In the 2004 final rule (69 FR 3698; January 26, 2004), the NRC adopted the following grandfathering provisions in § 71.19 for previously-approved packages:

- Packages approved under NRC regulations that were compatible with the provisions of the 1967 Edition of Safety Series No. 6 may be used for a 4-year period after adoption of the final rule, presuming fabrication was completed by August 31, 1986;
- Packages approved under NRC regulations that became effective on September 6, 1983 (see 48 FR 35600; August 5, 1983), which are compatible with the provisions of the 1973 or 1973 (as amended) Editions of Safety Series No. 6, may no longer be fabricated, but may still be used;
- Packages approved under NRC regulations that are compatible with the provisions of the 1985 or 1985 (as amended 1990) Editions of Safety Series No. 6, and designated as ''–85'' in the package identification number, may not be fabricated after December 31, 2006, but may still be used; and
- Package designs approved under any pre-1996 IAEA standards (*i.e.,* NRC packages with an ''–85'' or earlier package identification number) may be resubmitted to the NRC for review against the current NRC regulations. If the package design described in the resubmitted application meets the current NRC regulations, the NRC may issue a new CoC for that package design with a ''–96'' designation in the package identification number.

In that same 2004 rulemaking, the NRC did not revise its grandfathering provisions on special form radioactive material in § 71.4 because NRC

regulations were already consistent with the 1996 Edition of TS–R–1.

The NRC rulemaking in 2015 (80 FR 33988; June 12, 2015) made two minor changes to the transitional arrangements regulations. First, the grandfathering provision that was in § 71.19(a) for packages approved under NRC standards that were compatible with the provisions of the 1967 Edition of Safety Series No. 6 was deleted since that provision expired on October 1, 2008. Second, the definition of ''special form radioactive material'' was revised to allow special form radioactive material that was successfully tested using the current requirements of § 71.75(d) to continue to qualify as special form radioactive material, if the testing was completed before September 10, 2015.

Consistent with past practices, the NRC is proposing transitional arrangements to phase out older packages without a ''–85'' or ''–96'' in the package identification number, and limit use of packages with a ''–96'' to those whose fabrication has been completed by December 31, 2028, and consistent with DOT, limit fabrication of special form sources. The NRC determined that it is appropriate to begin a phased discontinuance of these older packages to further harmonize NRC's regulations with the IAEA standards in SSR–6, 2018 Edition. The DOT supports this discontinuation and coordinated with the IAEA on the update to its standards. While the NRC has not identified safety issues that necessitate the discontinuation of these older packages, they are no longer acceptable in jurisdictions that use the IAEA requirements. The NRC views that the advantages of consistent approvals across jurisdictions outweigh the value of retaining the authorization for these packages. The approach being taken is consistent with the NRC's 2004 rulemaking. Given this experience, the NRC does not expect that certificate holders will have challenges showing compliance with the regulations in effect at the time the application is submitted for revision.

The NRC is proposing to revise its transitional arrangements to be consistent with the IAEA, as follows:

1. Phase out the use of packages approved to NRC regulations that were harmonized with the IAEA's 1973 Edition and 1973 (as Amended) Edition of Safety Series No. 6, 8 years after the effective date of this rulemaking. These packages would be required to be recertified, removed from service, or used via exemption.

2. Prohibit the use of packages with a ''–96'' in the package identification number for which fabrication of the packaging was completed after December 31, 2028, and require multilateral approval (as defined in 49 CFR 173.403, ''Definitions'') for packages to be used for international shipment after December 31, 2025. Revise § 71.17(e) to state that packages with a ''–96'' in the package identification number would become previously approved packages and subject to the current § 71.19(c).

3. Coordinate with the DOT and make appropriate changes to § 71.4 to align with the definition of ''special form radioactive material'' that the DOT is proposing to adopt as part of their harmonization rulemaking, since DOT is the lead for certifying special form sources. The NRC is proposing to allow continued use of special form radioactive material that was approved to the regulations in effect from October 1, 2004 to the effective date of this rulemaking, provided they are fabricated on or before December 31, 2025.

4. Allow for package designs with a ''–96'' or earlier package identification number to be resubmitted to the NRC for review against the current standards. If the package design described in the resubmitted application meets the current standards, the NRC may issue a new CoC for that package design without a year designation.

The NRC notes that the IAEA eliminated the approval year in the package identification number for packages approved to SSR–6, 2018 Edition. Packages that were approved to NRC regulations harmonized with the 1973 Edition of Safety Series No. 6 do not have a year designation in the package identification number. To avoid confusion regarding these older packages, the NRC would revise all existing CoCs that do not have a ''–85'' or ''–96'' in their package identification number to add a provision that those CoCs cannot be renewed beyond the end date of the 8-year phase out period without being recertified to the revised version of 10 CFR part 71.

Issue 11. Inclusion of Head Space for Liquid Expansion

The NRC's regulation in § 71.87, ''Routine determinations,'' requires that before each shipment of licensed material, the licensee must ensure that the package, which includes its contents, satisfies the applicable requirements of part 71. One such requirement is that the licensee must determine in accordance with § 71.87(d) that any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid.

The NRC's requirement in § 71.87(d) is compatible with the DOT's regulations at 49 CFR 173.24(h)(1), ''General requirements for packagings and packages.'' That regulation requires: ''When filling packagings and receptacles for liquids, sufficient ullage (outage) must be left to ensure that neither leakage nor permanent distortion of the packaging or receptacle will occur as a result of an expansion of the liquid caused by temperatures likely to be encountered during transportation.''

The DOT's regulations in 49 CFR 173.412(k), ''Additional design requirements for Type A packages,'' contain a general design requirement for Type A packages designed to contain liquids to ensure that packages provide for ullage to accommodate variations in temperature of the contents. The term ''ullage'' refers to the unfilled space in a container, or the amount by which the contents of a container fall short of being full. Because DOT's regulations for Type AF, Type B, and Type BF packages refer to the NRC's regulations, DOT's regulations do not contain design requirements for Type AF, Type B, or Type BF packages. Type A, Type AF, Type B, and Type BF packages are defined in § 71.4, ''Packages.''

The IAEA standards in paragraph 649, SSR–6, 2018 Edition, require that ''The design of a package intended for liquid radioactive material shall make provision for ullage to accommodate variations in the temperature of the contents, dynamic effects and filling dynamics.''

The NRC regulations have an operational requirement in § 71.87(d) to ensure that for a system containing liquid, there is sufficient head space, or other specified provision to accommodate the expansion of liquid. The NRC does not, however, have a comparable design requirement for Type AF and Type B packages in 10 CFR part 71 to that in DOT's regulations. Even though the NRC's regulations do not include a comparable design requirement for ensuring sufficient space to allow for liquid expansion, any Type AF or Type B package design certified by the NRC must comply with § 71.87 and DOT regulations in 49 CFR 173.24(h) on ullage when being filled.

During review of applications for either a new CoC or an amendment to an existing CoC, the NRC reviews whether the requirements in § 71.87(d) are reflected in the operating procedures for packages with liquid contents. Each package approval issued by the NRC contains a condition to ensure that the package is prepared in accordance with the operating procedures in the

application. This ensures that all package users, whether NRC licensees or not, comply with the requirements listed in § 71.87, as appropriate for the package design.

Although the NRC regulations ensure that adequate ullage exists, the NRC has received on occasion an application that did not evaluate whether there was sufficient design space in a container with liquids. To clarify this requirement, the NRC is proposing to revise § 71.43, ''General standards for all packages,'' to add a design requirement for a package designed to contain liquids to ensure adequate ullage during evaluation of the tests and conditions for normal conditions of transport and hypothetical accident conditions.

Issue 12. Revision of Quality Assurance Program Biennial Reporting Requirements

On June 12, 2015, the NRC issued a final rule (80 FR 33988), updating the administrative procedures for the QAP requirements described in 10 CFR part 71, subpart H, ''Quality Assurance.'' Specifically, the NRC added § 71.106 to establish requirements for QAP changes and associated reporting requirements.

Previously, all changes made to QAP approvals had to be reviewed and approved by the NRC before they could be implemented. The provisions in § 71.106 allow changes to QAPs that do not reduce commitments, such as those that involve administrative improvements and clarifications, spelling corrections, and non-substantive changes, to be made and implemented without prior NRC approval. QAP changes that would reduce commitments require prior NRC approval.

In addition, § 71.106 requires that changes to QAPs that do not reduce commitments must be submitted to the NRC every 24 months. That final rule also specified, ''If a quality assurance program approval holder has not made any changes to its approved quality assurance program description during the preceding 24-month period, the approval holder will be required to report this to the NRC'' (80 FR 33994). In addition, the NRC's guidance document for 10 CFR part 71 QAPs, Regulatory Guide 7.10, Revision 3, was updated in conjunction with the 2015 final rule to state that if no changes were made to the QAP, a QAP approval holder would indicate to the NRC that no changes were made.

The requirement for a report, even if no changes were made during the preceding 24-month period, is necessary as the NRC inspection program for 10 CFR part 71 QAP approval holders relies on having current information about the QAP available to the NRC. The NRC considers the 24-month reporting requirement, including when no changes are made, as providing an appropriate balance between the burden placed on the QAP approval holders and the need to ensure that the NRC has current information for its oversight of these QAPs. Most QAP approval holders subject to periodic inspection are inspected every 5 years or on an as-needed basis. Another benefit to receiving a report even when no QAP changes have been made is that the QAP reporting requirements in 10 CFR part 71 would be consistent with those in §§ 50.54(a)(3) and 50.71(e)(2) for 10 CFR part 50 QAPs. Since the 2015 final rule became effective, the NRC has received questions and concerns from industry on this subject since the language in § 71.106 does not state that QAP approval holders must report even if there were no changes in the prior 24-month period.

The NRC is proposing to revise § 71.106(b) to clarify that a biennial report must be submitted to the NRC even if no changes are made to the QAP during the reporting period.

Issue 13. Deletion of Type A Package Limitations in Fissile Material General Licenses

The general license criteria in § 71.22 allow NRC licensees to ship small quantities of fissile material in packages that have been assigned a criticality safety index (CSI) to ensure accumulation control for packages on a conveyance. The provisions of § 71.22 require that (1) the fissile material is in a Type A package that meets the requirements of 49 CFR 173.417(a); (2) licensees have an NRC-approved QAP satisfying the provisions of 10 CFR part 71, subpart H; (3) there is no more than a Type A quantity of radioactive material; (4) there is less than 500 grams total of beryllium, graphite, or hydrogenous material enriched in deuterium; and (5) the package is labeled with a CSI that meets the limits in § 71.22(d). The regulation in § 71.22(e)(1) provides an equation to calculate package CSI:

$$\mathrm{CSI} = 10\left[\frac{\text{grams of } {}^{235}\mathrm{U}}{\mathrm{X}} + \frac{\text{grams of } {}^{233}\mathrm{U}}{\mathrm{Y}} + \frac{\text{grams of Pu}}{\mathrm{Z}}\right]$$

where X, Y, and Z are mass limits of ^{235}U, ^{233}U, and plutonium obtained from Table 71–1 (if ^{233}U or plutonium are present) or Table 71–2.

Similarly, the general license criteria in § 71.23 allow NRC licensees to ship small quantities of special form plutonium in packages that have been assigned a CSI to ensure accumulation control for packages on a conveyance. The provisions of § 71.23 require that (1) the fissile material is in a Type A package meeting the requirements of 49 CFR 173.417(a); (2) licensees have an NRC-approved quality assurance program satisfying the provisions of 10 CFR part 71, subpart H; (3) there is no more than a Type A quantity of radioactive material; (4) there is less than 1,000 grams of plutonium, provided that the total amount of ^{239}Pu and ^{241}Pu constitutes less than 240 grams of the plutonium in the package; and (5) the package is labeled with a CSI that meets the limits in § 71.23(d). The regulation in § 71.23(e)(1) provides an equation to calculate package CSI:

$$CSI = 10\left[\frac{grams\ of\ {}^{239}Pu + grams\ of\ {}^{241}Pu}{24}\right]$$

The calculations that support the mass limits in § 71.22 include conservative assumptions regarding neutron moderation and water reflection, *i.e.,* optimally moderated spheres of ^{235}U, ^{233}U, and ^{239}Pu with full water reflection. The mass limits in § 71.23 have a similar basis, but are higher for the two fissile plutonium isotopes, as the material is special form and will not redistribute significantly. In both cases, it is assumed that the

material will remain in the package under normal conditions of transport because of the Type A package requirement but can reconfigure outside of the package under hypothetical accident conditions. The limitation to a Type A quantity of radioactive material in a Type A package, however, is not consistent with the mass limits for some fissile nuclides in some cases (*e.g.,* the mass limits for ^{239}Pu in Table 71–1 are 37 grams or 24 grams, depending on the degree of moderation, while the A_2 value for ^{239}Pu is equivalent to 0.435 grams). In addition, the requirement in § 71.23 does not consistently refer to ''special form sealed sources'' in that paragraph (a) also refers to Pu-Be sealed sources. While all special form sources are sealed sources, not all sealed sources meet the definition of special form material in 10 CFR 71.4.

Removing the limitation to a Type A quantity of radioactive material in a Type A package would allow licensees to ship material under the general licenses in §§ 71.22 and 71.23 in a Type B package. When shipping material that meets the mass limits of the general licenses in §§ 71.22 and 71.23 in a Type B package, the criticality safety conclusions associated with these mass limits remain valid. In fact, the material would be less likely to present a criticality hazard, as Type B packages generally are more robust and have more mass, which would increase neutron absorption, limit releases under hypothetical accident conditions, and prevent material from multiple packages from redistributing together under optimum moderation conditions.

Revising the general licenses to authorize transport in a Type B package would also require conforming changes to § 71.0(d)(1). The regulations in § 71.0(d)(1) state that use of the general licenses in § 71.22 or § 71.23 does not require NRC approval. Package approval is not currently required by the NRC because the conditions of the general licenses require the contents to be in a Type A package. The regulations in § 71.14(b)(1) exempt the licensee from all requirements in 10 CFR part 71, except for §§ 71.5 and 71.88, when shipping a Type A quantity. Because the NRC is proposing to revise §§ 71.22 and 71.23 to authorize shipment of a Type B quantity of radioactive material, an NRC package approval would be required for shipment of the Type B quantity of radioactive material. The NRC package approval for the Type B quantity of radioactive material would not include evaluation of criticality safety because the criticality safety is assured for shipment of fissile material authorized under one of these general licenses.

While NRC is not proposing to revise §§ 71.22(b) and 71.23(b), which require that the licensee have an NRC-approved QAP. Applications for QAP approvals use a graded approach, based on the planned activities and shipments that a licensee plans to make. For example, if a licensee has a QAP that was approved for making only Type A shipments under § 71.22 or § 71.23, then the licensee would need to obtain additional NRC approval for a QAP that includes QA items necessary for making Type B shipments.

In addition, because the NRC is proposing to authorize shipments of Type B packages in §§ 71.22 and 71.23, the NRC is proposing to include three new paragraphs in §§ 71.22 and 71.23 that are similar to the requirements in § 71.17(c), (d), and (e). The NRC is proposing to add a new requirement in §§ 71.22(f) and 71.23(f) to ensure that, for shipments made using the respective general license, each licensee must comply with § 71.17(c), *i.e.,* the licensee must: (1) maintain a copy of the NRC approval, including all referenced documents; (2) comply with the terms and conditions of the NRC approval and the applicable requirements of subparts A, G, and H in 10 CFR part 71; and (3) prior to first use, register to use the package. A licensee is only required to register once to use a package, and therefore a licensee already registered to use the package via § 71.17 would not have to re-register to use the package under one of these two general licenses.

The NRC is proposing to add a new requirement in §§ 71.22(g) and 71.23(g) to state that, for a package to be used under the respective general license, the NRC package approval must state that the package can be used under the general license in either § 71.17 or the general license in § 71.22 or § 71.23. Authorizing use under the general license in § 71.17 would ensure that existing, approved Type B package designs could also be used to transport the material authorized by one of the two general licenses in § 71.22 or § 71.23.

Finally, the NRC is proposing to add a new requirement in §§ 71.22(h) and 71.23(h) to ensure that any Type B package used under the respective general license approved by the NRC before the effective date of the final rule is subject to the transitional arrangements in § 71.19. Issue 10 in Section III of this document describes the NRC's proposed changes to its transitional arrangements.

In summary, the NRC is proposing to remove the restriction in §§ 71.22 and 71.23 to ship Type A material in only a Type A package (*i.e.,* allowing shipment of material up to the mass limits in a Type B package); to add three new paragraphs in §§ 71.22 and 71.23; and to make conforming changes to § 71.0(d)(1). Additionally, the NRC is proposing to clarify that only special form sealed sources, not just sealed sources may be delivered to a carrier for transport using the general license in § 71.23.

Issue 14. Deletion of ^{233}U Restriction in Fissile General License

The general license criteria in § 71.22 allow NRC licensees to ship small quantities of fissile material in packages that have been assigned a CSI to ensure accumulation control for packages on a conveyance. General license users assign a CSI based on the equation in § 71.22(e)(1), and the fissile mass limits in either Table 71–1 or 71–2 to 10 CFR part 71. Table 71–2 contains mass limits for shipping uranium enriched to various weight percent levels in ^{235}U. However, § 71.22(e)(5) states in part that the lower mass values of Table 71–1 must be used if the enrichment level of uranium is unknown, if the amount of plutonium exceeds one percent of the mass of ^{235}U, or if ^{233}U is present in the package.

While ^{233}U is not present in natural uranium, it may be present in very low concentrations in some facilities that may have handled ^{233}U in the past. These contamination-level concentrations, while detectable with modern isotopic assay methods and physically ''present,'' are not important for criticality safety of ^{235}U transportation. The calculations used to support the enrichment limit for § 71.15(d), for up to 1.0 weight percent enriched uranium, demonstrate that this limit is safe provided the plutonium and ^{233}U are limited to less than one percent of the mass of ^{235}U. The same limitation could be applied to the use of Table 71–2 limits for shipping enriched uranium under § 71.22, without affecting criticality safety.

The NRC is therefore proposing to revise § 71.22 to limit the ^{233}U to less than one percent of the mass of ^{235}U, similar to the provision limiting plutonium in § 71.22(e)(5)(ii).

Issue 15. Other Recommended Changes to 10 CFR Part 71

As described in the draft regulatory basis, Issue 15 groups several topics identified by the NRC, some of which are not directly related to harmonizing NRC requirements with IAEA standards, and include clarifications to ensure compatibility with the DOT and

clarifications to Agreement State regulations.

Issue 15.1. Deletion of Duplicative Reporting Requirements

In the 2002 proposed rule (67 FR 21390, April 30, 2002), the NRC proposed changes to its reporting requirements in § 71.95, ''Reports.'' Those proposed changes would have: (1) required licensees to obtain certificate holder input before submitting an event report; (2) provided direction on the content of the written report; and (3) lengthened the reporting requirement date to 60 days, consistent with other reporting requirements in NRC regulations. The proposed rule recommended adding 71.95(a)(1) and (2) and 71.95(b), but not the current 71.95(a)(3).

In the final rule (69 FR 3697, January 26, 2004), the NRC stated that the proposed rule had inadvertently left out new paragraph (a)(3), mentioned in the proposed rule's regulatory analysis, that would retain the existing requirement for licensees to report instances of failure to follow the conditions of the CoC while a packaging was in use. Paragraph (a)(3) was thus added to the final rule. However, in adding that paragraph to the final rule, the NRC introduced duplicative language between it and paragraph (b).

The NRC is proposing to delete the duplicative text in paragraph (a)(3).

Issue 15.2. Revision of the Definition of Low Specific Activity

The NRC is proposing to modify the first sentence in the definition of ''Low Specific Activity (LSA) material'' in § 71.4 to change ''excepted under § 71.15'' to ''exempted under § 71.15.'' This change would make the definition of LSA in § 71.4 consistent with the title of § 71.15, ''Exemption from classification as fissile material'' and ensure that it is clear that LSA packages may contain fissile material up to the exemption limits in § 71.15.

Issue 15.3. Revision of Tables Containing A_1 and A_2 Values and Exempt Material Activity and Consignment Limits

The IAEA has made changes in SSR–6, 2018 Edition, related to the A_1 and A_2 activity values and the exempt material activity concentrations and exempt consignment activity limits. The DOT is the lead agency for information related to the A_1 and A_2 values and for the exempt material activity concentrations and exempt consignment activity limits, as provided in 49 CFR 173.435 and 173.436, respectively. The NRC has corresponding information in 10 CFR part 71, Appendix A, Tables A–1 and A–2.

To be considered radioactive material under DOT's regulations (*i.e.,* Class 7 (radioactive) material as defined in 49 CFR 173.403), the material must exceed both the nuclide specific exemption concentration limit and the consignment exemption activity limit. The A_1 and A_2 values are quantities of radioactivity that are used in the transportation regulations to determine the type of packaging necessary for a particular radioactive material shipment. Each radionuclide is assigned an A_1 and an A_2 value, where A_1 is the maximum activity of special form material that is permitted in a Type A package, and A_2 is the maximum activity of normal form radioactive material that is permitted in a Type A package as prescribed in 10 CFR 71.4 and 49 CFR 173.403. The NRC's and the DOT's transportation regulations include package activity limits based on fractions or multiples of the A_1 and A_2 values (*e.g.,* $10^{-3}A_2$ and $3{,}000A_2$, respectively).

In its concurrent harmonization rulemaking, the DOT is proposing to make changes to 49 CFR 173.435, ''Table of A_1 and A_2 values for radionuclides,'' and 173.436, ''Exempt material activity concentrations and exempt consignment activity limits for radionuclides,'' by adding seven radionuclides, including barium-135m, germanium-69, iridium-193m, nickel-57, strontium-83, terbium-149, and terbium-161. The NRC is proposing to make corresponding changes to Tables A–1 and A–2 to add these radionuclides. The NRC is proposing to revise the specific activity of natural rubidium (Rb(nat)) to correct an error that was introduced in the 1995 version of the rule. Table A–1 of Appendix A to 10 CFR part 71 gives the specific activity as 6.7×10^6 TBq/g, 1.8×10^8 Ci/g. However, the correct value for the specific activity of Rb(nat) is 670 Bq/g (6.7×10^{-10} TBq/g, 1.8×10^{-8} Ci/g). The A_1 and A_2 values were not impacted by this error and remain correct. The NRC is also proposing to revise footnote c at the end of Table A–2 to state that in the case of thorium-natural, the parent radionuclide is thorium-232, and in the case of uranium-natural, the parent radionuclide is uranium-238. Further, the NRC is proposing to editorially revise several other radionuclides to move the name of the element and its atomic number (shown in the second column of each table) to the first instance of that element alphabetically in the tables.

Issue 15.4. Revision to Agreement State Compatibility Categories

The NRC is proposing several changes to the compatibility category designations related to the QAP and reporting requirements. These changes would ensure that Agreement States have the appropriate authority to approve, inspect, and enforce QAPs for their licensees, as well as that the NRC and Agreement States receive important reports regarding issues with radioactive material shipments.

The NRC is proposing to revise the compatibility category designations for the regulations containing QAP requirements for those Agreement States that have licensees located within their States who use NRC-approved Type B packages, other than for industrial radiography, to ship Type B quantities of radioactive material; or have licensees that ship using the general license in § 71.21, ''General license: Use of foreign approved package''; § 71.22, ''General license: Fissile material''; or § 71.23, ''General license: Plutonium-beryllium special form material.'' The NRC is also proposing to revise the compatibility category designation for the reporting requirements in § 71.95.

In the 2004 final rule (69 FR 3697; January 26, 2004) that revised § 71.101, ''Quality assurance requirements,'' the NRC stated that § 71.101(b), and (c)(1) are designated as Compatibility Category C for those Agreement States that have licensees that use Type B packages, other than for industrial radiography. For Compatibility Category C, the essential objectives of the NRC program elements should be adopted by such Agreement States. The NRC is proposing to change the compatibility category designation for 71.101(b) and (c)(1) from C to B. This is consistent with Management Directive 5.9, ''Adequacy and Compatibility of Program Elements for Agreement State Programs,'' which states that program elements in Compatibility Category B are those that apply to activities that cross jurisdictional boundaries. Since the QAP activities in 71.101(b) and (c)(1) are used during domestic shipping of radioactive material and therefore cross jurisdictional boundaries, a B compatibility would align with Management Directive 5.9 criteria. Also, many of the regulations that contain QAP review criteria (*e.g.,* §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125) were addressed in the 2004 rule, but were designated as Compatibility Category NRC, which relate to areas of regulation reserved to the NRC that cannot be adopted by the Agreement States. The

NRC is proposing to address these compatibility issues in this proposed rule so that, consistent with the intent of the 2004 rulemaking, Agreement States can adopt compatible QAP regulations that would require their licensees to follow these QAP criteria and allow Agreement States to approve, inspect and enforce their licensees' QAPs. Specifically, this rule proposes to correct the compatibility category designation to B for many of these regulations that are currently Compatibility Category NRC, C, or D. This change would require Agreement States to have essentially identical regulations and would give the Agreement States the authority to approve, inspect and enforce their licensees' QAPs. Only Agreement States with licensees that use Type B packages, other than for industrial radiography, or with licensees that ship using the general license in § 71.21, § 71.22, or § 71.23, which also requires an approved QAP, would be impacted.

Additionally, the regulations in § 71.95 require NRC licensees to submit a written report to the NRC of instances in which there is a significant reduction in the effectiveness of any NRC-approved package; details of defects with safety significance in any NRC-approved package, after first use; and instances in which the conditions of a CoC were not followed during shipment. In the 2004 final rule (69 FR 3697; January 26, 2004) that revised § 71.95, the NRC stated that the compatibility category for § 71.95 is Category D; therefore, it does not need to be adopted by the Agreement States to be compatible with the NRC's regulatory program. The reporting requirements in § 71.95(a) are to ensure that the NRC is alerted to instances in which a package may have a defect or has a significant reduction in effectiveness such that, as needed, other licensees authorized to use the package are made aware of the possible issues. Agreement State licensees also use NRC-approved packages, including industrial radiography devices, but are not subject to any of the requirements in § 71.95 and, therefore, are not required to submit a report to the NRC pursuant to § 71.95. The NRC is proposing to change the compatibility category for § 71.95(a) to Compatibility Category C in order to have Agreement State regulations require notification to the NRC of these instances. This will clarify that if a State licensee uses an NRC-approved package that has a defect or has a significant reduction in effectiveness the NRC is aware such that others using the package can be made aware of the situation. The NRC also is proposing to update the compatibility category for § 71.95(b) to Compatibility Category C to ensure that the Agreement State agency receives these reports from its licensees indicating instances when the CoC was not followed. As noted in the 1995 final rule (60 FR 50248, 50259), the purpose of this requirement is to provide feedback on QAP effectiveness. Consistent with the compatibility category corrections for other QAP related regulations, this proposed rule would also correct the compatibility category for § 71.95(b) so that Agreement States receive these QAP-related reports. The compatibility categories for § 71.95(c) and (d) would also be revised to Compatibility Category C so that these reports contain the required information.

In summary, the NRC is proposing to revise the compatibility category for (1) § 71.101(b) and (c)(1) from a Compatibility Category C to B to be in alignment with the criteria in Management Directive 5.9; (2) many of the QAP-related regulations (*e.g.,* §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125) from a Compatibility Category NRC, C, or D to a B to allow the Agreement States the authority to approve, inspect and enforce these regulations; and (3) the reporting requirements in § 71.95(a) and (b) from a Compatibility Category D to C so that the NRC receives reports from Agreement State licensees on package defects pursuant to § 71.95(a), and that Agreement State regulators receive reports when their licensees do not use an NRC-approved package in accordance with the CoC pursuant to § 71.95(b), and to § 71.95(c) and (d) so that these reports contain the required information.

Issue 15.5. Deletion of Redundant Advance Notification Requirements for Shipment of Spent Nuclear Fuel

Section 71.97 is titled ''Advance notification of shipment of irradiated reactor fuel and nuclear waste.'' However, advance notification requirements for irradiated reactor fuel (and, equivalently, spent nuclear fuel) are separately included in the more general requirements of 10 CFR part 73, ''Physical protection of plants and materials.'' Specifically, as required in § 73.37(b)(2), licensees are required to provide advance notification of shipment to the Governor of a State and/or Tribal official for any shipment crossing the State or Tribal boundary when the shipment contains greater than 100 grams irradiated reactor fuel and the external radiation dose rate is greater than 1 Gy (100 rad) per hour at a distance of 1 meter (3.3 feet) from any accessible surface without intervening shielding. Licensees are also required to provide notification of such shipments to the NRC in accordance with § 73.72. Additionally, as required in § 73.35, ''Requirements for physical protection of irradiated reactor fuel (100 grams or less) in transit,'' licensees who transport 100 grams or less of irradiated reactor fuel, when the external radiation dose rate is greater than 1 Gy (100 rad) per hour at a distance of 1 meter (3.3 feet) from any accessible surface without intervening shielding, are required to provide advance notification of shipment in accordance with § 37.77. When 10 CFR part 37 was established in 2013, this requirement was introduced, but the ''irradiated reactor fuel'' aspect was not removed from § 71.97. Therefore, licensees may need to produce two reports for a single shipment to meet the advance notification requirements of §§ 71.97 and 73.37 or § 73.35. To address this potential inefficiency the NRC is proposing to modify § 71.97 to remove references to irradiated reactor fuel.

IV. Specific Request for Comment

The NRC is seeking comment and feedback from the public on this proposed rule. The NRC is particularly interested in comment and supporting rationale from the public on the following:

QUESTION 1: IAEA Changes in SSR–6 (2018 Edition) Not in the Scope of This Proposed Rule

Starting in 2016, while developing the regulatory basis for this proposed rule, the NRC considered the changes in SSR–6, 2012 Edition, and the proposed changes that were being considered for SSR–6, 2018 Edition, which were eventually issued in June 2018. The NRC contracted with Oak Ridge National Laboratory (ORNL) to develop ORNL/TM–2014/658, ''Comparison of the International and United States Domestic Radioactive Material Transport Regulations.'' In this document, ORNL compared both NRC and DOT regulations to SSR–6, 2012 Edition, and noted the differences. The NRC then compared the changes between SSR–6, 2018 Edition, and the 2012 Edition to determine which changes affect NRC regulations and whether those changes should be included in this proposed rule. Based on this review, the NRC did not include the following IAEA changes in the scope of this proposed rule:

1. Issue 1 consisted of four different sub-issues: Issue No. 1a: New Fissile

Exceptions in IAEA SSR–6, paragraph 417; Issue No. 1b: Competent Authority-Approved Fissile Exception, SSR–6, paragraph 417(f); Issue No. 1c: CSI-Controlled Fissile Material Packages, SSR–6, paragraph 674; and Issue No. 1d: Plutonium Shipments in Type A Packages, SSR–6, paragraph 675.

For issue 1a, the NRC considered whether to adopt the fissile exceptions in paragraphs 417(c), without consignment limits in paragraph 570(c); the consignment limit in paragraph 570(d) associated with the package mass limit in paragraph 417(d); and the exception in paragraph 417(e) and its associated exclusive use restriction in paragraph 570(e), but with a mass limit of 140 g instead of the IAEA mass limit of 45 grams of fissile material from SSR–6, 2018 Edition, into the NRC regulations. The NRC chose not to adopt the consignment limits in 570(c) and (d) for the fissile exceptions in 417(c) and 417(d), respectively because consignment limits do not prevent the accumulation of packages on a transport conveyance, as there is no limit to the number of consignments that may be present on a single conveyance. Additionally, the accumulation on a single conveyance of the number of these packages required to approach criticality is not credible.

After evaluation of Issue 1b, the NRC is not proposing to add the new ''competent authority-approved'' fissile exception in paragraph 417(f) into the NRC regulations. If an NRC licensee wished to ship a material that did not meet the fissile material exemption or general license criteria in 10 CFR part 71, and for which demonstration of subcriticality in a package per the requirements of §§ 71.55 and 71.59 is deemed too burdensome, the licensee could request a specific exemption under § 71.12. The NRC notes that if an NRC licensee submitted a ''competent authority-approved'' exception, the approval would include both NRC and DOT reviews and issuance of the exception and the NRC review and findings would be similar to those of either an exemption or NRC-issued CoC.

After evaluation of Issue 1c, the NRC is not proposing to add CSI-controlled fissile material packages that the IAEA incorporated into SSR–6, paragraph 674. The IAEA SSR–6, paragraph 674(a), contains fissile material mass limits (per Table 13 in SSR–6, paragraph 674) and a CSI determination for packages with a minimum external dimension of 10 centimeters, which are not required to withstand normal conditions of transport in SSR–6, paragraphs 719–724. The IAEA SSR–6, paragraph 674(b), contains similar fissile material mass limits, and a formula for determination of a lower CSI, for packages which withstand normal conditions of transport while maintaining a larger minimum external dimension of 30 centimeters. The IAEA SSR–6, paragraph 674(c), contains the same CSI calculation as paragraph 674(b), for packages that withstand normal conditions of transport while maintaining a minimum external dimension of 10 centimeters, with a limit of 15 grams fissile material per package.

The NRC does not propose to adopt the changes in IAEA SSR–6, paragraph 674, because the NRC has determined that the mass limits and other requirements in §§ 71.22 and 71.23 are appropriate for providing criticality safety equivalent to packages approved under the criticality safety requirements of §§ 71.55 and 71.59. Adopting the provisions of IAEA SSR–6 would result in more restrictive mass limits for the fissile material general licenses authorized under 10 CFR part 71.

The NRC evaluated issue 1d, SSR–6, paragraph 675, to add NRC requirements for shipment of plutonium in a nonfissile package, with accumulation control provided by the calculation of a CSI. This provision was included in SSR–6, 2012 Edition but without accumulation control. The NRC's fissile exemption in § 71.15(f) is similar in that it limits the package to 1000 g of plutonium, of which not more than 20 percent by mass may be plutonium-239, plutonium-241, or any combination of the two; however, the NRC regulation does not include accumulation control via a CSI calculation. The NRC has determined that the fissile exemption in § 71.15(f) is safe without accumulation control, and that there is no safety benefit to limiting accumulation through the use of a CSI, in order to be consistent with the IAEA standards. Therefore, the NRC is not proposing to harmonize with paragraph 675, SSR–6, 2018 Edition.

2. The NRC considered adopting the reduced external pressure value of 60 kPa from paragraph 645 and the air transport package requirements from paragraph 621. The NRC is not proposing to harmonize with paragraphs 621 and 645, SSR–6, 2018 Edition, as discussed for Issue 2 in Section III of this proposed rule, to avoid creating unnecessary mode-specific restrictions within 10 CFR part 71.

3. Inclusion of Type C Package Standards (paragraphs 669–672)—The NRC considered adding Type C package standards for domestic transport, but there was not an expressed need for domestic transport of packages approved to Type C standards. Therefore, the NRC is not proposing to add Type C package standards in this proposed rule.

4. Testing and reporting the integrity of the containment system and shielding, and assessing criticality safety (paragraph 716), and additional description of the impact of the tests on packages (paragraphs 718–737)—The NRC reviewed its regulations for an application for approval of a package design and considered its regulations sufficient to obtain the information needed to determine whether a package design meets the requirements in 10 CFR part 71.

5. Addition of LSA Fissile Shipments (paragraphs 518, 519, 520)—Since LSA packages are self-certified under DOT regulations, other than the fissile material exemptions (§ 71.15) and fissile material general licenses (§§ 71.22 and 71.23), there is no mechanism for adding fissile material to an LSA package without NRC approval. Under current NRC regulations, the package could be certified but would become a Type BF or Type AF package, depending on the quantity of radioactive material in the package, and therefore the NRC did not consider any revision necessary.

6. Safety Factors for Lifting Attachments (paragraph 608)—The NRC regulations in § 71.45 contain quantitative criteria for evaluating lifting attachments that are considered a structural part of the package. The IAEA standards state an ''appropriate'' safety factor must be used. In its review, the NRC determined that adopting the IAEA changes would not result in safety benefits beyond those in § 71.45.

7. Shipment after Storage and Gap Analysis (paragraphs 503(e) and 809(k))—The IAEA added regulations both for shipment after storage and a gap analysis for packages in storage prior to shipment. The regulations in SSR–6, paragraph 503(e), require that during storage, packages are maintained to ensure that all relevant transportation standards in SSR–6 and certificates of approval for those packages will be fulfilled. The NRC is not proposing to adopt paragraph 503(e) because, during its review of packages for which storage is expected prior to transport (*i.e.,* dual purpose casks or canisters), the NRC ensures that the evaluations, operating procedures, maintenance program and acceptance tests for transport take storage into consideration. In addition, for any package that is stored prior to transport, existing NRC requirements (§§ 71.17(c) and 71.87(b)) ensure that, prior to transport, the licensee must comply with the terms and conditions

of the NRC approval for the package design and ensure the package is in unimpaired physical condition. Following the operating procedure, maintenance program, and acceptance tests in the application is a condition of approval in all NRC-approved CoCs.

The NRC is not proposing to adopt paragraph 809(k), which requires ''periodic evaluation of changes of regulations, changes in technical knowledge and changes of the state of the package design during storage.'' The NRC's transitional arrangements authorize continued use of package designs approved to prior versions of the NRC regulations, with limitations on fabrication and restrictions on modifications to package designs without the need to demonstrate full compliance with the revised regulations. Package designs compliant with the existing regulations do not become ''unsafe'' when the regulations are revised (unless a significant safety issue is corrected in the revision). If a significant safety issue is corrected in a rulemaking, NRC certificate holders for that package design or type of package would be informed via generic communication (*e.g.,* regulatory information summary, bulletin, or generic letter), and as appropriate, required to take action, prior to a potential rule change. In addition, as stated previously, prior to transport the licensee must comply with the terms and conditions in the NRC approval and ensure the package is in unimpaired physical condition.

• Is there anything in SSR–6, 2018 Edition, that the NRC did not include in the scope of this proposed rule, but should have? In your comment, please explain why the NRC should consider adding the change to the final rule and the associated benefits.

QUESTION 2: Removing Tables A–1 Through A–4 in Appendix A to 10 CFR Part 71

The NRC transportation regulations in 10 CFR part 71 include appendix A to 10 CFR part 71, ''Determination of A_1 and A_2.'' The introductory material in paragraphs I–V to appendix A includes information related to determining A_1 and A_2 values. Appendix A includes four tables:

—Table A–1: ''A_1 and A_2 Values for Radionuclides''
—Table A–2: ''Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides''
—Table A–3: ''General Values for A_1 and A_2''
—Table A–4: ''Activity-Mass Relationships for Uranium''

The Secretary of Transportation has the authority to regulate the transportation of hazardous materials per the Hazardous Materials Transportation Act, as amended and codified in 49 U.S.C. 5101, *et seq.* The Secretary is authorized to issue regulations to implement the requirements of the statute. The DOT's Pipeline and Hazardous Materials Safety Administration has been delegated the responsibility for the hazardous materials regulations, which are contained in 49 CFR parts 100–185. These regulations include the requirements for Class 7 (radioactive) material.

The DOT maintains the same information in 49 CFR 173.433 through 49 CFR 173.436 as found in the NRC's appendix A to 10 CFR part 71. With the authority to regulate the transportation of hazardous materials, including Class 7 (radioactive) material, DOT is the lead agency for determining the basic radionuclide values (A_1 and A_2 values) and the exempt material activity concentrations and exempt consignment activity limits for radionuclides that are used in radioactive material transportation activities. The DOT regulations include:

—49 CFR 173.433, ''Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels''
—49 CFR 173.433, Table 7, ''General Values for A_1 and A_2''
—49 CFR 173.433, Table 8, ''General Exemption Values''
—49 CFR 173.434, ''Activity-mass relationships for uranium and natural thorium''
—49 CFR 173.435, ''Table of A_1 and A_2 values for radionuclides''
—49 CFR 173.436, ''Exempt material activity concentrations and exempt consignment activity limits for radionuclides''

The NRC recognizes challenges associated with maintaining the accuracy and consistency of all the information in appendix A to 10 CFR part 71 with the parallel information in 49 CFR chapter I, considering, in part, the periodic updates the DOT makes to these regulations to harmonize with IAEA standards. Therefore, to minimize duplicative information within the domestic transportation regulations, and to recognize the DOT's authority to regulate Class 7 (radioactive) material, the NRC is considering removing the content of appendix A to 10 CFR part 71. Where it is necessary within the subparts of 10 CFR part 71, the NRC would remove all references in 10 CFR chapter I to information in appendix A to 10 CFR part 71 and replace those with references to the appropriate regulation in 49 CFR chapter I.

• Please comment on whether the NRC should consider removing Tables A–1 through A–4 in appendix A to 10 CFR part 71 and instead refer to the appropriate DOT tables in 49 CFR chapter I, rather than updating Tables A–1 through A–4 in appendix A to 10 CFR part 71 as currently shown in this proposed rule. If so, would there be a benefit to members of the public, including applicants and licensees? Please explain your rationale.

QUESTION 3: Merits of Requiring a Biennial Report for No Changes to a QAP

As described in Section III of this document, in Issue 12, the NRC is proposing to revise § 71.106 to achieve NRC's stated intent in the 2015 final rule. Specifically, the NRC is proposing to revise § 71.106(b) to clarify that a biennial report must be submitted to the NRC even if no changes are made to the QAP during the reporting period. This proposed requirement would benefit the NRC's regulatory oversight of QAP approval holders. The NRC inspection program for 10 CFR part 71 QAP approval holders relies on having current information about the QAP available to the NRC, including the reporting of no changes. The 24-month reporting period aims to provide an appropriate balance between the burden placed on the QAP approval holders and the need to ensure that the NRC has current information, especially when considering most QAP approval holders subject to periodic inspection are inspected every 5 years or on an as-needed basis. Another benefit is that the revised QAP reporting requirements in 10 CFR part 71 would be consistent with those in 10 CFR 50.54(a)(3) and 50.71(e)(2) for 10 CFR part 50 QAPs. The benefits and costs of the proposed requirement are described in the regulatory analysis and the NRC estimates that the cost of compliance is very small. The NRC is interested in the public's feedback as to the benefits and costs of requiring a no-change biennial report.

• Please comment on the benefits and costs of requiring a 10 CFR part 71 QAP approval holder to submit a biennial report to the NRC even if no changes are made to the QAP during the reporting period.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes in this proposed rule.

Section 71.0 Purpose and Scope

This proposed rule would revise paragraph (d)(1) to clarify general license package approval requirements.

Section 71.4 Definitions

This proposed rule would revise the definitions for *Low Specific Activity material, Special form radioactive material,* and *Surface Contaminated Object,* delete the definition for *Low Specific Activity—III Leaching Test,* and add a new definition for *Radiation level.*

Section 71.15 Exemption From Classification as Fissile Material

This proposed rule would revise the introductory paragraph by replacing (f) with (g), paragraph (a) by adding new subparagraphs (1) and (2), paragraph (d) by replacing ''of up to'' with ''not exceeding, and add paragraph (g), which is a new provision for exclusive use of transportation packages.

Section 71.17 Exemption From Classification as Fissile Material

This proposed rule would revise paragraph (e) to change the design approval date for Type B or fissile material packages from April 1, 1996, to the effective date of the final rule.

Section 71.19 Previously Approved Package

This proposed rule would revise paragraph (a) to include existing CoCs that have a ''–96'' in their package identification number, redesignate paragraphs (c) and (d) as paragraphs (d) and (e), revise newly redesignated paragraph (e) to include those CoCs that have a suffix ''–96'' in their identification numbers, and add new paragraph (c), to add transitional arrangements on existing CoCs that have a ''–96'' in their package identification number.

Section 71.22 General License: Fissile Material

This proposed rule would revise paragraph (a) to replace ''subparts E and F of this part'' with ''§§ 71.55 and 71.59'' and to remove the limitation to a Type A quantity of radioactive material in a Type A package to allow shipment of material under the general licenses in §§ 71.22 and 71.23 in a Type B package, paragraph (c) to remove (c)(1) and redesignate paragraph (c)(2) as new paragraph (c), paragraphs (e)(3) through (5) to limit the ^{233}U to less than one percent of the mass of ^{235}U, similar to the provision limiting plutonium in § 71.22(e)(5)(ii), and add new paragraphs (f) through (h) to ensure that each licensee will comply with § 71.17(c) for shipments made using the respective general license and that any Type B package used under the respective general license approved by the NRC before the effective date of the final rule is subject to the transitional arrangements in § 71.19.

Section 71.23 General License: Plutonium-Beryllium Special Form Material

This proposed rule would revise paragraphs (a) and (c), and add paragraphs (f) through (h) to clarify that only special form sealed sources, not just sealed sources may be delivered to a carrier for transport using the general license in § 71.23.

Section 71.31 Contents of Application

This proposed rule would revise paragraph (a) to add a maintenance program description, as required by § 71.35 among the contents of application.

Section 71.35 Package Evaluation

This proposed rule would revise paragraph (b) to delete ''and'' paragraph (c) to add ''; and'' and add new paragraph (d) to specify maintenance program requirements.

Section 71.43 General Standards for All Packages

This proposed rule would revise paragraph (d) to specifically include the evaluation of the effects of aging, and to specify that degradation evaluations will be managed by the maintenance program in accordance with § 71.35(d), and add new paragraph (i) to specify that each system designed to contain liquids has adequate ullage during evaluation of the tests and conditions for normal conditions of transport and hypothetical accident conditions specified in §§ 71.71 and 71.73.

Section 71.55 General Requirements for Fissile Material Packages

This proposed rule would revise paragraph (g)(1) to require that there is no contact between the cylinder plug and any other part of the packaging, other than at its original attachment point and that the cylinder plug remains leak tight, as NRC requires for the cylinder valve.

Section 71.71 Normal Conditions of Transport

This proposed rule would change the unit of measure in the table in paragraph (c)(1) to change the unit of measure for the values of insolation used for the heat test for normal conditions of transport from ''(g cal/cm^2)'' to ''(W/m^2)''.

Section 71.73 Hypothetical Accident Conditions

This proposed rule would revise paragraph (b) to add insolation to the initial conditions for the tests for hypothetical accident conditions.

Section 71.77 Qualification of LSA—III Material

This proposed rule would remove and reserve § 71.77 and make conforming changes to §§ 71.4 and 71.100.

Section 71.95 Reports

This proposed rule would remove paragraph (a)(3) as it is duplicative to text in paragraph (b).

Section 71.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

This proposed rule would revise the section title, the introductory text of paragraph (b), and paragraphs (d) and (f)(1) to remove references to irradiated reactor fuel to correct a duplicative advance notification reporting requirement in § 71.97 with those in §§ 73.35 and 73.37.

Section 71.100 Criminal Penalties

This proposed rule would revise paragraph (b) to remove the leaching test requirement as a conforming change to § 71.77.

Section 71.106 Changes to Quality Assurance Program

This proposed rule would revise the introductory text of paragraph (b) to clarify that a biennial report must be submitted to the NRC even if no changes are made to the QAP during the reporting period.

Appendix A to Part 71—Determination of A_1 and A_2

This proposed rule would revise Tables A–1 and A–2 in paragraph V.b. to add seven radionuclides and correct the specific activity of natural rubidium.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this proposed rule will not, if issued, have a significant economic impact on a substantial number of small entities. This proposed rule affects a number of ''small entities'' as defined by the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). However, as indicated in the regulatory analysis, these amendments do not have a significant economic impact on the affected small entities.

VII. Regulatory Analysis

The NRC has prepared a regulatory analysis on this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC and includes consideration of the costs and benefits of updating guidance. The NRC requests public comment on the regulatory analysis. The regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document. Comments on the regulatory analysis may be submitted to the NRC as indicated under the **ADDRESSES** section of this document.

VIII. Backfitting and Issue Finality

The NRC has determined that backfitting (§ 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 it would not involve any provisions that would impose backfits as defined in 10 CFR chapter I or affect the issue finality of any approval issued under 10 CFR part 52. Some licensees that are within the scope of the backfit rule (*e.g.,* a power reactor or a fuel fabrication facility) transport radioactive material from their own facilities. Those backfitting and issue finality provisions apply to activities directly regulated under those parts, and do not apply to activities regulated under other parts that do not include backfitting or issue finality provisions. The exception to this general principle is where the activity regulated under other parts that do not include backfitting or issue finality provisions is an inextricable part of the regulated activity within the scope of backfitting or issue finality. Preparing packages for transport is not an inextricable part of the procedures or organization required to design, construct or operate a facility as licensed under 10 CFR part 50, 52, 70, 72, or 76; rather, it is a separate activity that these licensees may choose to undertake. The scope of this proposed rule does not include any changes to any of those facilities or plants' activities for which the backfit rule applies.

The NRC's determination on this matter is in accordance with Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,'' and its associated guidance in NUREG–1409, ''Backfitting Guidelines.''

IX. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (*e.g.,* rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge that may result from a licensee or impacted entity implementing a number of complex regulatory actions, programs, or requirements within limited available resources.

To better understand the potential CER implications incurred due to this proposed rule, the NRC is requesting comment on the following questions. Responding to these questions is voluntary, and the NRC will respond to any comments received in the final rule.

1. 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?
2. If current or projected CER challenges exist, what should be done to address this situation? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?
3. Do other regulatory actions (from the NRC or other agency) influence the implementation of the proposed rule's requirements?
4. 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?
5. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The Commission has preliminarily determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The basis of this determination is as follows: The amendments would change the requirements for packaging and transportation of radioactive material. The amendments would make changes to harmonize the NRC's regulations with the 2018 Edition of the IAEA's transport standards (SSR–6) and with that of the DOT's regulations under 49 CFR and include NRC-initiated changes. The environmental impacts arising from the changes have been evaluated and would not involve any significant environmental impact. This includes consideration of direct, indirect, and cumulative impacts. Other amendments are procedural in nature and would have no significant impact on the environment.

The preliminary determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the **ADDRESSES** caption. The environmental assessment is available as indicated under the ''Availability of Documents'' section of this document.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and has requested comments.

XII. Paperwork Reduction Act

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: Harmonization of Transportation Safety Requirements with IAEA Standards.

The form number if applicable: Not applicable.

How often the collection is required: Applications for changes reducing commitments to the NRC on quality assurance programs and for package approval are submitted on occasion. Quality assurance program reporting on changes determined not to reduce commitments, or reporting of no

changes made, is done every 24 months. Reporting packaging issues or instances in which the conditions in a CoC are not followed occur infrequently.

Who will be required or asked to report: General or specific licensees who use a package, certificate holders and applicants for a new or amended CoC.

An estimate of the number of annual responses: 7.5.

The estimated number of annual respondents: 6.5.

An estimate of the total number of hours needed annually to complete the requirement or request: 1,376.7 hours (an increase of 1,052.5 hours reporting + an increase of 322.7 third party disclosure hours and 1.5 hours recordkeeping).

Abstract: The NRC, in consultation with the DOT, is proposing to amend its regulations for the packaging and transportation of radioactive material. The Commission has historically been consistent in its support of harmonizing the NRC transportation regulations with the IAEA's standards. These amendments would make the NRC regulations conform to the recent revisions to the IAEA standards for the international transportation of radioactive material and maintain consistency with the DOT regulations. These changes are necessary to maintain a consistent regulatory framework for the packaging and transportation of radioactive material. The NRC is also proposing to amend these regulations to include administrative, editorial, or clarifying changes, including changes to certain Agreement State compatibility category designations.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule 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 of the proposed information collection 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 proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package is available in ADAMS under Accession No. ML20101F920. You may obtain information and comment submissions related to the OMB clearance package by searching on *https://www.regulations.gov* under Docket ID NRC–2016–0179.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2016–0179.
- *Mail comments to:* FOIA, Library, and Information Collections Branch T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to *Infocollects.Resource@nrc.gov.*
- *Submit to OMB Directly:* Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this document to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function.

Comments on the information collections will be publicly available in ADAMS and on *Reginfo.gov.* Submit comments by November 14, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

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. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this proposed rule that would 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. With the following exception, none of the proposed amendments would change the manner in which criminal penalties would be assessed or enforced.

Criminal penalties as they apply to regulations in 10 CFR part 71 are discussed in § 71.100. One of the actions within the scope of this rulemaking, Issue 6, Deletion of the Low Specific Activity—III Leaching Test, proposes to remove the content of § 71.77 and replace the section heading with ''RESERVED.'' This change would impact § 71.100(b), because § 71.77 would be removed from that paragraph as the leaching test would no longer be required.

XIV. Coordination With NRC Agreement States

The NRC has coordinated with the Agreement States throughout the development of this proposed rule. Agreement State representatives have served on the rulemaking working group that developed this proposed rule and on the Standing Committee on Compatibility for the rulemaking. The NRC also provided a preliminary draft of the proposed rule to the Agreement States for review.

XV. Compatibility of Agreement State Regulations

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017 and published in the **Federal Register** on October 18, 2017 (82 FR 48535), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC, or adequacy category Health and Safety (H&S). Compatibility Category A program elements are 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 Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B program elements are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C program elements are those program elements that do not meet the criteria of Category A or B but do contain the essential objectives that 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 national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D program elements are those program elements that do not meet any of the criteria of Category A, B, or C and, therefore, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC program elements are those program elements that address areas of regulation that cannot be relinquished to the

Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of title 10 of the *Code of Federal Regulations.* These program elements should not be adopted by the Agreement States. Adequacy category H&S program elements are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program. A bracketed compatibility category (*e.g.,* [B]) means that the provision may have been adopted elsewhere in the Agreement State's regulations and does not need to be adopted again.

As discussed in Section III of this document, Issue 15.4, the regulations that contain QAP requirements (*e.g.,* §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125) are currently designated as Compatibility Category NRC and cannot be adopted by the Agreement States. Since a proper QAP review cannot be completed without addressing many of these criteria, Agreement States would need to adopt compatible regulations to require licensees that use NRC-approved Type B packages for shipping, other than for industrial radiography, or that ship using the general license in § 71.21, § 71.22 or § 71.23, to follow these QAP criteria. Additionally, since only a few Agreement States have applicable licensees that perform shipments of Type B quantities of radioactive materials, other than for industrial radiography operations (which are covered under § 34.31), or that ship using the general license in § 71.21, § 71.22, or § 71.23, all QAP-related requirements, including those mentioned previously and others referenced below in the table, would be re-designated as a Compatibility Category B. This re-designation would require those Agreement States with applicable licensees to have essentially identical regulations. For those Agreement States that do not have applicable licensees, these regulations will remain designated as Compatibility Category D and, hence, do not have to be adopted for purposes of compatibility.

The changes in this proposed rule, discussed in Section III of this document, would be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. Regulations that are a part of this rulemaking but remain the same compatibility category designation are included in the table for completeness. The compatibility categories are designated in the following table.

Section	Change	Subject	Compatibility	
			Existing	New
71.0(d)(1)	Revised	Purpose and Scope	D	D
71.4	New	Definition: Radiation Level		[A]
71.4	Revised	Definition: Low Specific Activity (LSA) material [Deletion of Low Specific Activity—III Leaching Test].	[B]	[B]
71.4	Revised	Definition: Special form radioactive material	[B]	[B]
71.4	Revised	Definition: Surface Contaminated Object (SCO)	[B]	[B]
71.15(a) and (d)	Revised	Exemption from classification as fissile material	[B]	[B]
71.15(g)	New	Exemption from classification as fissile material		[B]
71.17(e)	Revised	General license: NRC-approved package	B	B
71.19	Revised	Previously approved package	NRC	NRC
71.22(a), (c), and (e)(3) through (5)	Revised	General license: Fissile material	[B]	[B]
71.22(f) through (h)	New	General license: Fissile material		[B]
71.23(a) and (c)	Revised	General license: Plutonium-beryllium special form material.	[B]	[B]
71.23(f) through (h)	New	General license: Plutonium-beryllium special form material.		[B]
71.31(a)	Revised	Contents of application	NRC	NRC
71.35(b) and (c)	Revised	Package evaluation	NRC	NRC
71.35(d)	New	Package evaluation		NRC
71.43(d)	Revised	General standards for all packages	NRC	NRC
71.43(i)	New	General standards for all packages		NRC
71.55(g)	Revised	General requirements for fissile material packages	NRC	NRC
71.71(c)(1)	Revised	Normal conditions of transport	NRC	NRC
71.73(b)	Revised	Hypothetical accident conditions	NRC	NRC
71.77	Removed	Qualification of LSA—III Material	NRC	
71.95	Revised compatibility category.	Reports	D	** C
71.95(a)(3)	Removed	Reports	D	*
71.97	Revised	Advance notification of shipment of irradiated reactor fuel and nuclear waste.	B	B
71.100	Revised	Criminal penalties	D	D
71.101(b)	Revised compatibility category.	Quality assurance requirements	*** C	*** B
71.101(c)(1)	Revised compatibility category.	Quality assurance requirements	*** C	** B
71.103(a) and (b)	Revised compatibility category.	Quality assurance organization	*** C	** B
71.103(c), (d), (e) and (f)	Revised compatibility category.	Quality assurance organization	D	** B
71.105	Revised compatibility category.	Quality assurance program	C	** B
71.106	Revised compatibility category.	Changes to quality assurance program	C	** B
71.109	Revised compatibility category.	Procurement document control	NRC	** B

Section	Change	Subject	Compatibility	
			Existing	New
71.111	Revised compatibility category.	Instructions, procedures and drawings	NRC	** B
71.113	Revised compatibility category.	Document control	NRC	** B
71.115	Revised compatibility category.	Control of purchased material, equipment, and services.	NRC	** B
71.117	Revised compatibility category.	Identification and control of materials, parts and components.	NRC	** B
71.119	Revised compatibility category.	Control of special processes	NRC	** B
71.121	Revised compatibility category.	Internal inspection	NRC	** B
71.123	Revised compatibility category.	Test control	NRC	** B
71.125	Revised compatibility category.	Control of measuring and test equipment	NRC	** B
71.127	Revised compatibility category.	Handling, storage, and shipping control	[C]	** B
71.129	Revised compatibility category.	Inspection, test, and operating status	[C]	** B
71.131	Revised compatibility category.	Nonconforming materials, parts, or components	[C]	** B
71.133	Revised compatibility category.	Corrective action	C	** B
71.135	Revised compatibility category.	Quality assurance records	*** C	** C
71.137	Revised compatibility category.	Audits	C	** C
Table A–1 in Appendix A to 10 CFR Part 71.	Revised	A_1 and A_2 Values for Radionuclides	[B]	[B]
Table A–2 in Appendix A to 10 CFR Part 71.	Revised	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides.	[B]	[B]

* Denotes regulations that are designated Compatibility Category D but which will be removed from the regulations as a result of these proposed amendments. Agreement States that have an equivalent regulation should remove these provisions from their regulations when the regulations become final.

** B/C (as designated)—for Agreement States that have licensees that use Type B approved packages for shipping, other than for industrial radiography, or have licensees that ship using the general license in § 71.21, § 71.22, or § 71.23, these regulations are required for compatibility purposes.

D—for States that do not have licensees that use Type B approved packages for shipping, other than for industrial radiography, these regulations are not required for compatibility purposes.

*** 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.17(b) and therefore will satisfy those sections referenced in this provision (§§ 71.101 through 71.137).

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9, ''Adequacy and Compatibility of Program Elements for Agreement State Programs,'' for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule on the basis of comments received and Commission decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations to do so during the comment period.

XVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 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 would revise regulations associated with packaging and transportation of radioactive material in 10 CFR part 71 to conform NRC regulations to the recent revisions to the IAEA standards for the international transportation of radioactive material. While the rule harmonizes NRC requirements with IAEA Standard SSR–6, it does not endorse SSR–6, and SSR–6 does not meet the criteria for being a voluntary consensus standard under the NTTAA. The NRC is not aware of any voluntary consensus standard that could be used. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain how the voluntary consensus standard is comparable and why it should be used. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII. Availability of Guidance

The NRC is issuing for comment draft guidance, DG–7011, ''Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material,'' Revision 3 to Regulatory Guide 7.9, for the implementation of the requirements in this proposed rule. The draft guidance identifies the information to be provided in an application for package approval and establishes a uniform format for presenting that information. The draft guidance is available in ADAMS under Accession No. ML22223A085. You may obtain information and comment submissions related to the draft guidance by

searching on *https://www.regulations.gov* under Docket ID NRC–2016–0179. You may submit comments on the draft regulatory guidance by the methods outlined in the **ADDRESSES** section of this document.

The NRC considered whether a revision of NUREG–1608, ''Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects,'' was warranted in association with this proposed rule. NUREG–1608, published jointly by the NRC and the DOT in 1998, provides guidance to shippers of LSA material and SCO regarding significant changes to both 10 CFR part 71 and 49 CFR that became effective April 1, 1996. The NRC's judgement is that NUREG–1608 serves the purpose for which it was intended, which was to educate shippers about major changes to the regulations in 1996, and that the minor changes to the LSA and SCO requirements in this proposed rule do not warrant a revision to NUREG–1608.

The NRC also considered whether a revision of NUREG–1660, ''U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments,'' was warranted in association with this proposed rule. NUREG–1660, published jointly by the NRC and the DOT in 1999, provides summaries of NRC, DOT, and other regulations that shippers must meet, depending on the type of material being shipped. NUREG–1660 is currently under revision to incorporate requirements issued in both 10 CFR chapter I and 49 CFR chapter I since 1999. The NRC's judgement is that there are no changes being considered in this proposed rule that will affect the content of the revised NUREG–1660.

The NRC considered whether a revision to NUREG–1886, ''Joint Canada—United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages,'' is warranted in association with this rulemaking. NUREG–1886, published jointly with the DOT and the Canadian Nuclear Safety Commission (CNSC) in 2009, provides a standard format and content of an application for approval of Type B(U) and fissile material packages to demonstrate the ability of the given package to meet both United States (NRC and DOT regulations) and Canadian regulations. The NRC, the DOT, and the CNSC recently started discussions to update NUREG–1886, which will be a multiyear effort. When NUREG–1886 is updated, the NRC will ensure that it is consistent with the final version of DG–7011 and its associated Regulatory Guide 7.9.

The NRC considered whether a revision to NUREG–2216, ''Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material,'' is warranted in association with this proposed rule. NUREG–2216, which was recently issued, provides guidance to the NRC staff for reviewing an application for package approval issued under 10 CFR part 71. There are no changes being considered in this proposed rule that would significantly affect the content of NUREG–2216. The NRC will first obtain experience using NUREG–2216 to evaluate whether there are more significant changes needed before making the relatively minor changes associated with this proposed rule.

XVIII. Public Meeting

The NRC will conduct a public meeting on this proposed rule to describe it to the public and to facilitate the development of public comments. The NRC will publish a notice of the location, time, and agenda of the meeting on *Regulations.gov* and on the NRC's public meeting website at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*

XIX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/ **Federal Register** citation
Rulemaking Documents and References	
SECY–20–0102 for this proposed rule	ML20101F921
Federal Register notice for this proposed rule	ML22209A035
Regulatory Analysis for this proposed rule	ML22209A039
Environmental Assessment for this proposed rule	ML22209A045
OMB supporting statement for this proposed rule	ML22209A052
Draft regulatory basis document for this rulemaking, dated March 2019	ML18262A185
Federal Register notification for draft regulatory basis, dated April 12, 2019	84 FR 14898
Draft regulatory basis comment submission #1	ML19106A347
Draft regulatory basis comment submission #2	ML19113A064
Draft regulatory basis comment submission #3	ML19143A311
Draft regulatory basis comment submission #4	ML19143A312
Draft regulatory basis comment submission #5	ML19148A147
Draft regulatory basis comment submission #6	ML19149A474
Draft regulatory basis comment submission #7	ML19150A140
NRC final rule amending packaging and transportation of radioactive material regulations, dated June 12, 2015.	80 FR 33988
DOT final rule amending packaging and transportation of radioactive material regulations, dated July 11, 2014.	79 FR 40589
NRC final rule harmonizing its regulations with the 1996 edition of IAEA Safety Series No. 6, dated January 26, 2004.	69 FR 3697
NRC proposed rule harmonizing its regulations with the 1996 edition of IAEA Safety Series No. 6, dated April 30, 2002.	67 FR 21390
NRC final rule harmonizing its regulations with the 1985 edition of IAEA Safety Series No. 6, dated September 28, 1995.	60 FR 50248
NRC/DOT Memorandum of Understanding, dated July 2, 1979	44 FR 38690
SECY–16–0093, ''Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,'' dated July 28, 2016.	ML16158A164

Document	ADAMS accession No./web link/ **Federal Register** citation
Staff Requirements Memorandum SRM–SECY–16–0093, ''Staff Requirements—SECY–16–0093—Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,'' dated August 19, 2016.	ML16235A182
Harmonization issues paper, ''Issues Paper on Potential Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,'' dated November 15, 2016.	ML16299A298 paper, ML16299A291 package
Federal Register notification for harmonization issues paper, dated November 21, 2016	81 FR 83171
Issues paper public meeting summary, ''Summary of the December 5 and 6, 2016 Public Meeting on Issues Paper on Revisions to Transportation Safety Requirements and Harmonization with the International Atomic Energy Agency Transportation Requirements,'' dated December 14, 2016.	ML16343A661
Draft Regulatory Guidance Document	
Draft Regulatory Guide DG–7011, ''Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material,'' Revision 3 of Regulatory Guide 7.9.	ML22223A085
IAEA Transportation Safety Standards and Related References	
SSR–6, ''Regulations for the Safe Transport of Radioactive Material,'' 2018 Edition	*https://www.iaea.org/publications/12288/regulations-for-the-safe-transport-of-radioactive-material*
SSR–6, ''Regulations for the Safe Transport of Radioactive Material,'' 2012 Edition	*https://www.iaea.org/publications/8851/regulations-for-the-safe-transport-of-radioactive-material-2012-edition*
TS–R–1, ''Regulations for the Safe Transport of Radioactive Material,'' 2009 Edition	*https://www.iaea.org/publications/8005/regulations-for-the-safe-transport-of-radioactive-material-2009-edition*
TS–R–1, ''Regulations for the Safe Transport of Radioactive Material,'' 2005 Edition	*https://www.iaea.org/publications/7291/regulations-for-the-safe-transport-of-radioactive-material-2005-edition*
TS–R–1, ''Regulations for the Safe Transport of Radioactive Material,'' 1996 Edition	*https://www.iaea.org/publications/6056/regulations-for-the-safe-transport-of-radioactive-material-1996-edition-revised*
Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended in 1990)''.	*http://gnssn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_006_1990.pdf*
Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material,'' 1985 Edition	*https://gnssn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_006_1985.pdf*
Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material,'' 1973 Edition	*https://gnssn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_006_1973.pdf*
Safety Series No. 6, ''Regulations for the Safe Transport of Radioactive Material,'' 1967 Edition	*https://gnssn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_006_1967.pdf*
Other International Standards References	
ANSI N14.1–2012, ''Nuclear Materials—Uranium Hexafluoride—Packagings for Transport,'' dated December 3, 2012.	*https://webstore.ansi.org/standards/pcc/ansin142012*
ANSI N14.5–2014, ''American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment,'' dated June 19, 2014.	*https://webstore.ansi.org/standards/pcc/ansin142014*
International Organization for Standardization 7195:2005, ''Nuclear Energy—Packaging of Uranium Hexafluoride (UF_6) for Transport,'' dated September 2005.	*https://www.iso.org/standard/31251.html*
American National Standards Institute/American Nuclear Society 8.1–2014 (Reaffirmed 2018), ''Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,'' American Nuclear Society, La Grange Park, IL.	*https://webstore.ansi.org/Standards/ANSI/ANSIANS2014R2018*
Miscellaneous References	
National Renewable Energy Laboratory Solar Radiation Data	*https://www.nrel.gov/gis/assets/images/solar-annual-ghi-2018-usa-scale-01.jpg*
NRC letter to Agreement States, ''Clarification of Title 10 of the *Code of Federal Regulations,* Part 71 Requirements Identified in Regulation Amendment Tracking System Identification Number RATS ID: 2015–3 (STC–17–060),'' dated August 15, 2017.	ML17213A844
Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998	63 FR 31885
Agreement State Program Policy Statement, dated October 18, 2017	82 FR 48535
NRC Management Directive 5.9, Handbook 5.9, ''Adequacy and Compatibility of Program Elements for Agreement State Programs,'' dated April 26, 2018.	ML18081A070
NRC Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,'' dated September 20, 2019.	ML18093B087

Document	ADAMS accession No./web link/ **Federal Register** citation
ORNL/TM–2014/658, ''Comparison of the International and United States Domestic Radioactive Material Transport Regulations,'' dated September 30, 2014.	*https://rampac.energy.gov/docs/default-source/doeinfo/ORNL-TM-2014-658.pdf*
NUREG–1409, ''Backfitting Guidelines,'' Revision 1, draft for public comment, dated March 2020.	ML18109A498
NUREG–1608, ''Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects,'' dated July 1998.	ML15336A927
NUREG–1660, ''U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments,'' dated January 1999.	*https://rampac.energy.gov/docs/default-source/nrcinfo/nureg_1660.pdf*
NUREG–1886, ''Joint Canada–United States Guide for Approval of Type B(U) and Fissile Material Transportation Packages,'' dated March 2009.	ML090930197
NUREG–2216, ''Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material,'' dated August 2020.	ML20234A651

Throughout the development of this proposed rule, the NRC may post documents related to it, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2016–0179. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2016–0179); (2) click the ''Subscribe'' link; and 3) enter an email address and click on the ''Subscribe'' link.

List of Subjects in 10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Packaging and containers, Penalties, 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. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR part 71:

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

Authority: Atomic Energy Act of 1954, 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 of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 180 (42 U.S.C. 10175); 44 U.S.C. 3504 note. Section 71.97 also issued under Sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

■ 2. In § 71.0, revise paragraph (d)(1) to read as follows:

§ 71.0 Purpose and scope.

* * * * *

(d)(1) Exemptions from the requirement for license in § 71.3 are specified in § 71.14. The general license in § 71.21 does not require NRC package approval. The general licenses in §§ 71.22 and 71.23 require NRC package approval if the quantities exceed a Type A quantity. The general license in § 71.17 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license.

* * * * *

■ 3. Amend § 71.4 by:

■ a. Revising the definitions for *Low Specific Activity material* and *Special form radioactive material;*

■ b. Revising the introductory text and add paragraph (3) for *Surface contaminated object;* and

■ c. Adding the definition *Radiation level* in alphabetical order.

The revisions and addition read as follows:

§ 71.4 Definitions.

* * * * *

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

* * * * *

(3) LSA—III. Solids (*e.g.,* consolidated wastes, activated materials), excluding powders, 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.); and

(ii) [Reserved]

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

* * * * *

Radiation level means the radiation dose equivalent rate expressed in millisieverts per hour or mSv/h (millirems per hour or mrem/h).

* * * * *

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 from April 1, 1996, to September 30, 2004, may continue to be used, provided that fabrication of the special form encapsulation was successfully completed by [DATE ONE DAY PRIOR TO EFFECTIVE DATE OF FINAL RULE]. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect from October 1, 2004, to [DATE ONE DAY PRIOR TO EFFECTIVE DATE OF FINAL RULE] may continue to be used, provided that fabrication of the special form encapsulation is successfully completed by December 31, 2025. Any other special form encapsulation must meet the specifications of this definition.

* * * * *

Surface contaminated object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of three groups with surface activity not exceeding the following limits:

* * * * *

(3) SCO—III: A large solid object which, because of its size, cannot be

transported in a type of package described in 49 CFR 173.403 of the DOT regulations and for which:

(i) All openings are sealed to prevent release of radioactive material during conditions defined in 49 CFR 173.427(d);

(ii) The inside of the object is as dry as practicable;

(iii) The nonfixed contamination on the external surface does not exceed the contamination limits specified in the DOT regulations in 49 CFR 173.443; and

(iv) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 does not exceed 8×10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 8×10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

* * * * *

■ 4. In § 71.15, revise the introductory text and paragraphs (a) and (d) and add paragraph (g) to read as follows:

§ 71.15 Exemption from classification as fissile material.

Fissile material meeting the requirements of at least one of the paragraphs (a) through (g) of this section are exempt from classification as fissile material and from the fissile material package standards of §§ 71.55 and 71.59 but are subject to all other requirements of this part, except as noted.

(a) Individual package containing:

(1) 2 grams or less fissile material, or

(2) 3.5 grams or less uranium-235, provided the uranium is enriched in uranium-235 to a maximum of 5 percent by weight, and the total plutonium and uranium-233 content does not exceed 1 percent of the mass of uranium-235.

* * * * *

(d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content not exceeding 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.

* * * * *

(g) Packages transported under exclusive use on a conveyance containing a total of 140 grams or less fissile material.

■ 5. In § 71.17, revise paragraph (e) to read as follows:

§ 71.17 General license: NRC-approved package.

* * * * *

(e) For a Type B or fissile material package, the design of which was approved by NRC before [EFFECTIVE DATE OF FINAL RULE], the general license is subject to the additional restrictions of § 71.19.

■ 6. Amend § 71.19 by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e);

■ c. Adding new paragraph (c); and

■ d. Revising newly redesignated paragraph (e).

The revisions and addition read as follows:

§ 71.19 Previously approved package.

(a) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation ''–85'' or ''–96'' in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with § 71.85(c);

(2) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging; and

(3) Paragraph (a) of this section expires [DATE 8 YEARS AFTER EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

(c) A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the NRC with the designation ''–96'' in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package must be satisfactorily completed by January 1, 2029, as demonstrated by application of its model number in accordance with § 71.85(c); and

(2) A package used for a shipment to a location outside the United States, after December 31, 2025, is subject to multilateral approval, as defined in the DOT's regulations at 49 CFR 173.403.

* * * * *

(e) NRC will revise the package identification number to designate previously approved package designs that were designated as AF, B(U), B(M), B(U)F, B(M)F, B(U)–85, B(U)F–85, B(M)–85, B(M)F–85, AF–85, B(U)–96, B(U)F–96, B(M)–96, B(M)F–96, or AF–96 as appropriate, with the identification number suffix AF, B(U), B(M), B(U)F, B(M)F, after receipt of an application demonstrating that the design meets the requirements of this part.

■ 7. In § 71.22, revise paragraphs (a), (c), and (e)(3) through (5) and add paragraphs (f) through (h) to read as follows:

§ 71.22 General license: Fissile material.

(a) A general license is issued to any licensee of the Commission to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of §§ 71.55 and 71.59. However, the material must be contained in a Type A or Type B package, consistent with the quantity of radioactive material in the package.

* * * * *

(c) The general license applies only when a package's contents contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

* * * * *

(e) * * *

(3) The values of X, Y, and Z used in the CSI equation must be taken from Table 71–1 or 71–2, as appropriate based on criteria from § 71.22(e)(4) and (5).

(4) If Table 71–2 is used to obtain the value of X, then:

(i) The total mass of plutonium and uranium-233 must not exceed 1 percent of the mass of uranium-235;

(ii) Values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

(iii) The value of the uranium enrichment must be known and be less than the enrichment value used from Table 71–2.

(5) Table 71–1 values for X, Y, and Z must be used to determine the CSI if:

(i) The total mass of plutonium and uranium-233 exceeds 1 percent of the mass of uranium-235;

(ii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iii) Substances having a moderating effectiveness (*i.e.,* an average hydrogen density greater than H_2O) (*e.g.,* certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping. * * *

* * * * *

(f) Each licensee using the general license under paragraph (a) of this section to transport a Type B quantity of licensed material must use a package for

which a license, CoC, or other approval has been issued by the NRC, and must comply with the provisions in § 71.17(c).

(g) For shipment of a Type B quantity of licensed material, this general license applies only when the package approval authorizes use of the package under the general license in § 71.17 or this general license.

(h) For a Type B package, the design of which was approved by NRC before [EFFECTIVE DATE OF FINAL RULE], this general license is subject to the additional restrictions of § 71.19.

■ 8. In § 71.23, revise paragraph (a) and the introductory text of paragraph (c) and add paragraphs (f) through (h) to read as follows:

§ 71.23 General license: Plutonium-beryllium special form material.

(a) A general license is issued to any licensee of the Commission to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sources, or to deliver Pu-Be special form sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of §§ 71.55 and 71.59. However, the fissile material must be contained in a Type A or Type B package, consistent with the quantity of radioactive material in the package.

* * * * *

(c) The general license applies only when a package's contents contain less than 1000 grams of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

* * * * *

(f) Each licensee using the general license under paragraph (a) of this section to transport a Type B quantity of licensed material must use a package for which a license, CoC, or other approval has been issued by the NRC, and must comply with the provisions in § 71.17(c).

(g) For shipment of a Type B quantity of licensed material, this general license applies only when the package approval authorizes use of the package under the general license in § 71.17 or this general license.

(h) For a Type B package, the design of which was approved by NRC before [EFFECTIVE DATE OF FINAL RULE], this general license is subject to the additional restrictions of § 71.19.

■ 9. In § 71.31, revise paragraph (a) to read as follows:

§ 71.31 Contents of application.

(a) An application for an approval under this part must include, for each proposed packaging design, the following information:

(1) A package description as required by § 71.33;

(2) A package evaluation as required by § 71.35;

(3) A maintenance program description, as required by § 71.35; and

(4) A quality assurance program description, as required by § 71.37, or a reference to a previously approved quality assurance program.

* * * * *

■ 10. In § 71.35, revise paragraphs (b) and (c) and add paragraph (d) to read as follows:

§ 71.35 Package evaluation.

* * * * *

(b) For a fissile material package, the allowable number of packages that may be transported in the same vehicle in accordance with § 71.59;

(c) For a fissile material shipment, any proposed special controls and precautions for transport, loading, unloading, and handling and any proposed special controls in case of an accident or delay; and

(d) A maintenance program to assure that the packaging will perform as intended throughout its time in service. The maintenance program must include periodic testing requirements, inspections, and replacement criteria and schedules for replacement and repairs of components on an as-needed basis.

■ 11. In § 71.43, revise paragraph (d) and add paragraph (i) to read as follows:

§ 71.43 General standards for all packages.

* * * * *

(d) A package must be made of materials and construction that assure that there will be no significant chemical, galvanic, or other reaction among the packaging components, among package contents, or between the packaging components and the package contents, including possible reaction resulting from inleakage of water, to the maximum credible extent. The effects of the aging mechanisms and the behavior of materials under irradiation must be evaluated on package components to show that their performance is not significantly degraded or that degradation will be managed by the maintenance program in accordance with § 71.35(d).

* * * * *

(i) Each system designed for holding liquids must be designed, constructed, and prepared for shipment so that under the tests specified in §§ 71.71 and 71.73, there would be adequate space to accommodate variations in temperature of the liquid, dynamic effects, and filling dynamics.

■ 12. In § 71.55, revise paragraph (g)(1) to read as follows:

§ 71.55 General requirements for fissile material packages.

* * * * *

(g) * * *

(1) Following the tests specified in § 71.73 (''Hypothetical accident conditions''), there is no physical contact between the valve body or the plug and any other component of the packaging, other than at its original point of attachment, and the valve and plug remain leak tight;

* * * * *

■ 13. In § 71.71, in the table in paragraph (c)(1), revise the heading of the second column to read as follows:

§ 71.71 Normal conditions of transport.

* * * * *

(c) * * *

(1) * * *

INSOLATION DATA

* * *	Total insolation for a 12-hour period (W/m^2)
* * * * *	

* * * * *

■ 14. In § 71.73, revise paragraph (b) to read as follows:

§ 71.73 Hypothetical accident conditions.

* * * * *

(b) Test conditions. Except for the water immersion test, the following conditions shall apply before and after the tests:

(1) The ambient air temperature shall remain constant at that value between −29 °C (−20 °F) and +38 °C (+100 °F) which is most unfavorable for the feature under consideration;

(2) The insolation shall be that value between 0 and the maximum value listed in the Insolation Data Table in § 71.71(c)(1), which is most unfavorable for the feature under consideration; and

(3) The initial internal pressure within the containment system must be the maximum normal operating pressure, unless a lower internal pressure, consistent with the ambient temperature assumed to precede and follow the tests, is more unfavorable.

* * * * *

§ 71.77 [Removed and Reserved]

■ 15. Remove and reserve § 71.77.

§ 71.95 [Amended]

■ 16. In § 71.95, remove paragraph (a)(3).

§ 71.97 [Amended]

■ 17. In § 71.97:

■ a. In the section heading, remove the phrase ''irradiated reactor fuel and'';

■ b. In paragraph (b) introductory text, remove the word ''also'';

■ c. In paragraph (d) introductory text and paragraphs (d)(1) and (2), remove the phrase ''irradiated reactor fuel or''; and

■ d. In paragraph (f)(1), remove the phrase ''an irradiated reactor fuel or'' and add in its place the word ''a''.

§ 71.100 [Amended]

■ 18. In § 71.100(b), remove the reference ''71.77,''.

■ 19. In § 71.106, revise the introductory text of paragraph (b) to read as follows:

§ 71.106 Changes to quality assurance program.

* * * * *

(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). If no changes were made to the quality assurance program this information shall also 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:

* * * * *

■ 20. In appendix A to part 71, in paragraph V.b.:

■ a. In Table A–1, add the entries for Ba-135m, Ge-69, Ir-193m, Ni-57, Sr-83, Tb-149, and Tb-161 in alphanumeric order and revise the entries for Ni-59, Rb(nat), and Tb-157; and

■ b. In Table A–2, add the entries for Ba-135m, Ge-69, Ir-193m, Ni-57, Sr-83, Tb-149, and Tb-161 in alphanumeric order and revise the entries for Ni-59, Tb-157, Th(nat), and U(nat).

The additions and revisions read as follows:

Appendix A to Part 71—Determination of A_1 and A_2

* * * * *

V.b. * * *

TABLE A–1—A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
*	*	*	*	*	*	*	*
Ba-135m		2.0×10^{1}	5.4×10^{2}	6.0×10^{-1}	1.6×10^{1}	3.0×10^{4}	8.1×10^{5}
*	*	*	*	*	*	*	*
Ge-69		1.0×10^{0}	2.7×10^{1}	1.0×10^{0}	2.7×10^{1}	4.3×10^{4}	1.2×10^{6}
*	*	*	*	*	*	*	*
Ir-193m		4.0×10^{1}	1.1×10^{3}	4.0×10^{0}	1.1×10^{2}	2.4×10^{3}	6.4×10^{4}
*	*	*	*	*	*	*	*
Ni-57	Nickel (28)	6.0×10^{-1}	1.6×10^{1}	5.0×10^{-1}	1.4×10^{1}	5.7×10^{4}	1.5×10^{6}
Ni-59		Unlimited	Unlimited	Unlimited	Unlimited	3.0×10^{-3}	8.0×10^{-2}
*	*	*	*	*	*	*	*
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	6.7×10^{-10}	1.8×10^{-8}
*	*	*	*	*	*	*	*
Sr-83		1.0×10^{0}	2.7×10^{1}	1.0×10^{0}	2.7×10^{1}	4.3×10^{4}	1.2×10^{6}
*	*	*	*	*	*	*	*
Tb-149	Terbium (65)	8.0×10^{-1}	2.2×10^{1}	8.0×10^{-1}	2.2×10^{1}	1.9×10^{5}	5.1×10^{6}
Tb-157		4.0×10^{1}	1.1×10^{3}	4.0×10^{1}	1.1×10^{3}	5.6×10^{-1}	1.5×10^{1}
*	*	*	*	*	*	*	*
Tb-161		3.0×10^{1}	8.1×10^{2}	7.0×10^{-1}	1.9×10^{1}	4.3×10^{3}	1.2×10^{5}
*	*	*	*	*	*	*	*

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)
*	*	*	*	*	*
Ba-135m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
*	*	*	*	*	*
Ge-69		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
*	*	*	*	*	*
Ir-193m		1.0×10^{4}	2.7×10^{-7}	1.0×10^{7}	2.7×10^{-4}

TABLE A–2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES—Continued

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)
*	*	*	*	*	*
Ni-57	Nickel (28)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Ni-59		1.0×10^{4}	2.7×10^{-7}	1.0×10^{8}	2.7×10^{-3}
*	*	*	*	*	*
Sr-83		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
*	*	*	*	*	*
Tb-149	Terbium (65)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Tb-157		1.0×10^{4}	2.7×10^{-7}	1.0×10^{7}	2.7×10^{-4}
*	*	*	*	*	*
Tb-161		3.0×10^{1}	8.1×10^{2}	7.0×10^{-1}	1.9×10^{1}
*	*	*	*	*	*
Th(nat) (b), (c)		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
*	*	*	*	*	*
U(nat) (b), (c)		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
*	*	*	*	*	

* * * * *

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

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

[c] In the case of Th(nat), the parent nuclide is Th-232; in the case of U(nat), the parent nuclide is U-238.

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Dated August 22, 2022.

For the Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

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