

# **Public Meeting on Proposed Rule**

## **Harmonization of NRC Transportation Safety Requirements with IAEA Standards**

October 26, 2022

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# Purpose

- Provide information to facilitate stakeholders comments on the “Harmonization of Transportation Safety Requirements with IAEA Standards” (87 FR 55708) proposed rule and draft regulatory guidance (DG-7011, “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material” (ML22223A085)
- The NRC is not collecting comments on the proposed rule and draft regulatory guidance during this meeting.

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# Agenda

- Welcome and Logistics
- Opening Remarks
- Background and Status
- Overview of the Proposed Rule and Draft Guidance
  - Opportunities for Questions
- Resources for Preparing and Submitting Comments
- Next Steps
- Questions and Discussion

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# Logistics

- Audience members will be admitted as attendees with their microphones disabled
- During “Questions and Discussion” periods, please indicate your desire to speak by using the “Raise Hand” button in Teams (or by pressing “\*5” if participating by phone)
- Once your name has been called by the facilitator, you will need to unmute yourself (press “\*6” if you are on the phone)
- Chat feature is also enabled
- Presentation slides shown on the Microsoft Teams screen and in ADAMS at ML22286A071
- Phone attendees should email [James.Firth@nrc.gov](mailto:James.Firth@nrc.gov) for attendance

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# Opening Remarks

Tara Inverso

Deputy Director

Division of Rulemaking, Environmental, and Financial Support

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# Background and Status

James Firth

Project Manager

Division of Rulemaking, Environmental, and Financial Support

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## Background on Harmonization and Compatibility with DOT Regulations

- The NRC periodically conducts rulemakings to harmonize the NRC's regulations with the IAEA's safety standards requirements and to maintain compatibility with the U.S. Department of Transportation's (DOT) regulations.
- Issues Paper on Potential Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements (81 FR 83171; November 21, 2016).
  - Public meeting was held December 5–6, 2016.
  - 14 issues documented in the paper.

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# Background on Harmonization and Compatibility with DOT Regulations

- Draft regulatory basis published for comment (84 FR 14898; April 12, 2019).
  - 14 issues from the Issues Paper;
  - Several NRC-identified changes, including clarifications to ensure compatibility with the DOT and changes to the compatibility categories for Agreement State regulations.
  - 4 alternatives considered for each issue:
    - 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.
  - Public meeting was held April 30, 2019. Meeting summary: [ML16343A661](#).

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## Status of Harmonization and Compatibility with DOT Regulations

- The NRC is proposing changes to Regulatory Guide 7.9 and has published draft regulatory guide 7011, “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material,” for public comment.
- The proposed rule was published in the *Federal Register* on September 12, 2022 (87 FR 55708) with a 75-day comment period.
  - The comment period ends November 28, 2022.
- The DOT published a related proposed rule on September 12, 2022 (87 FR 55743) with a 90-day public comment period.

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## Proposed Rule and Related Documents

- **Regulations.gov Docket: NRC-2016-0179**
  - <https://www.regulations.gov/docket/NRC-2016-0179>
- **Proposed Rule**
  - Citation: 87 FR 55708 (September 12, 2022)
  - <https://www.govinfo.gov/content/pkg/FR-2022-09-12/pdf/2022-18520.pdf>
- **Supporting & Related Material**
  - Draft Regulatory Analysis ([ML22209A039](#))
  - Draft Environmental Assessment ([ML22209A045](#))
  - Draft Supporting Statement for Information Collections ([ML22209A052](#))

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# Proposed Rule and Related Documents

- **Correction notice**

- Forthcoming

- **Corrections and Changes**

- Corrected information collection
    - Changed the number of responses from 7.5 to 100 and the number of respondents from 6.5 to 99
    - The overall burden does not change (rounded to a total of 1,377 hours)
    - Comment period for the information collection extended until November 28, 2022
  - Republished Draft Regulatory Analysis (correcting a publication error)
  - Clarified the units for the mass limit (changed “140 g” to “140 grams”)

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# Proposed Rule and Related Documents

- **Guidance Document**

- Draft Regulatory Guide DG-7011, “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material” ([ML22223A085](#))
- Unofficial redline/strikeout comparison between DG-7011 and Regulatory Guide 7.9, (Revision 2), “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material” (ML22280A061)

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# Overview of the Proposed Rule

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## Revision of Reduced External Pressure Test for Normal Conditions of Transport

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 2) (pages 55711–55712)

**Which sections of the CFR would be amended?**

- None – no change

**What are the current and proposed compatibility categories?**

- No change

- **Summary:**

- The NRC has decided not to pursue any changes to the reduced external pressure test requirement under § 71.73(c)(3)

- **Additional information:**

- The current 25 kPa (3.6 psia) would be retained

# Deletion of the Low Specific Activity (LSA)-III Leaching Test

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 6) (page 55713)

**Which sections of the CFR would be amended?**

- 10 CFR 71.4, 71.77, 71.100

**What are the current and proposed compatibility categories?**

- Unchanged

- **Summary:**

- The IAEA eliminated the LSA-III leaching test in SSR-6, 2018 Edition
- NRC proposes revising §§ 71.4, 71.77, and 71.100 to eliminate the LSA-III leaching test

- **Additional information:**

- Less burden on licensees with no decrease in safety

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# Inclusion of New Definition for Surface Contaminated Object

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 7) (pages 55713 –55714)

**Which sections of the CFR would be amended?**

- 10 CFR 71.4

**What are the current and proposed compatibility categories?**

- [B] → [B]

- **Summary:**

- NRC proposes to add a definition of a third group of SCO (i.e., SCO-III) in § 71.4 that would align with the DOT's definition for SCO-III

- **Additional information:**

- Decommissioning activities can include transporting large radioactive objects
- Efficiencies are gained and burden is removed with the addition of the SCO-III definition

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# Revision of the Definition of Low Specific Activity

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 15.2) (page 55719)

**Which sections of the CFR would be amended?**

- 10 CFR 71.4

**What are the current and proposed compatibility categories?**

- [B] → [B]

- **Summary:**

- NRC proposes to revise the definition of “low specific activity” in § 71.4

- **Additional information:**

- The change from “excepted under § 71.15” to “exempted under § 71.15” would align the definition with the section heading for § 71.15

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## Revision of Tables Containing $A_1$ and $A_2$ Values and Exempt Material Activity and Consignment Limits

### Where is this discussed in the FRN?

- Section III.C. (Issue Number 15.3) (page 55719)

### Which sections of the CFR would be amended?

- 10 CFR 71, Appendix A, Tables A-1 and A-2

### What are the current and proposed compatibility categories?

- [B] → [B]

- **Summary:**

- NRC proposes revising 10 CFR 71, Appendix A, Tables A-1 and A-2

- **Additional information:**

- Seven radionuclides would be added
- Footnote c for Thorium-natural would be revised
- Alphabetical listing of radionuclides would be revised
- Would align with DOT

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# Revision of Fissile Exemptions

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 1) (page 55711)

**Which sections of the CFR would be amended?**

- 10 CFR 71.15

**What are the current and proposed compatibility categories?**

- [B] → [B] and [--] → [B]

- **Summary:**

- NRC proposes to add two new fissile exemptions in § 71.15
- The fissile exemptions are similar to the new fissile exceptions in IAEA SSR-6

- **Additional information:**

- Would add an exemption for 3.5 grams  $^{235}\text{U}$  in uranium enriched up to 5.0 weight percent under § 71.15(a)
- Would add an exemption for up to 140 grams fissile material shipped exclusive use under § 71.15(g)

# Deletion of Type A Package Limitations in Fissile Material General Licenses

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 13) (pages 55717 - 55718)

**Which sections of the CFR would be amended?**

- 10 CFR 71.22 and 10 CFR 71.23

**What are the current and proposed compatibility categories?**

- [B] → [B] and [--] → [B]

- **Summary:**

- NRC proposes revisions to the General Licenses in §§ 71.22 and 71.23 to allow the use of Type B packaging
- NRC proposes adding paragraphs (f), (g), and (h) to each requirement, containing requirements if Type B packaging is used

- **Additional information:**

- Some mass limits in current rule language are greater than Type A (e.g., plutonium and  $^{233}\text{U}$ )
- Mass limits would not change, but licensees would now be able to use General License with Type B packaging

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# Deletion of $^{233}\text{U}$ Restriction in Fissile General License

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 14) (page 55718)

**Which sections of the CFR would be amended?**

- 10 CFR 71.22

**What are the current and proposed compatibility categories?**

- [B] → [B]

- **Summary:**

- NRC proposes revising the General License in § 71.22 to modify the restriction on  $^{233}\text{U}$  for using lower mass limits in Table 71-1
- Current language in § 71.22(e)(5)(i) requires more restrictive mass limits if “Uranium-233 is present in the package”
- Proposed language would require more restrictive mass limits if  $^{233}\text{U}$  mass is more than 1% of  $^{235}\text{U}$  mass

- **Additional information:**

- New language is similar to existing restriction on plutonium mass in § 71.22(e)(5)(ii)

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# Questions and Discussion

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# Type C Package Standards

**Where is this discussed in the FRN?**

- Section III.C.(Issue Number 3) (pages 55712)

**Which sections of the CFR would be amended?**

- None

**What are the current and proposed compatibility categories?**

- N/A

- **Summary:**

- NRC proposes to not add Type C standards to 10 CFR Part 71 due to no existing or anticipated need for domestic transport

- **Additional information:**

- No anticipated need for domestic transport of Type C package based on comments received on the Regulatory Basis
- Type C packages can still be approved for international transport via DOT regulations

# Insolation

**Where is this discussed in the FRN?**

- Section III.C. ((Issue Number 4) (pages 55712–55713)

**Which sections of the CFR would be amended?**

- 10 CFR 71.71(c)(1) and 10 CFR 71.73(b)

**What are the current and proposed compatibility categories?**

- NRC → NRC

- **Summary:**

- Proposing to change the units for insolation in § 71.71(c)(1) to metric units (from “g cal/cm<sup>2</sup>” to “W/m<sup>2</sup>”)
- Proposing to revise the test conditions in § 71.73(b) to include insolation as an initial condition to the tests for hypothetical accident conditions

- **Additional information:**

- Insolation is the amount of solar radiation reaching a given area

# Inclusion of Definition for Radiation Level

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 5) (page 55713)

**Which sections of the CFR would be amended?**

- 10 CFR 71.4

**What are the current and proposed compatibility categories?**

- [--] → [A]

- **Summary:**

- Would add the following definition to harmonize with IAEA definitions:  
Radiation level means the radiation dose equivalent rate expressed in millisieverts per hour or mSv/h (millirems per hour or mrem/h)

- **Additional information:**

- No change in burden on licensees with no decrease in safety

# Revision of Uranium Hexafluoride Package Requirements

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 8) (page 55714)

**Which sections of the CFR would be amended?**

- 10 CFR 71.55(g)(1)

**What are the current and proposed compatibility categories?**

- NRC → NRC

- **Summary:**

- Would add uranium hexafluoride cylinder plug in § 71.55(g)
- Would require 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

- **Additional information:**

- Ensures same requirement for the cylinder plug and valve

## Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program

### Where is this discussed in the FRN?

- Section III.C. (Issue Number 9) (pages 55714–55715)

### Which sections of the CFR would be amended?

- 10 CFR 71.35(d) 10 CFR 71.43(d)

### What are the current and proposed compatibility categories?

- [--] → NRC and NRC → NRC

- **Summary:**

- Would add a requirement in § 71.35(d) for the application for package approval to include a description of the package maintenance program
- Would revise § 71.43(d) to include the evaluation of the effects of aging

- **Additional information:**

- IAEA added requirement for applications for package approval include a maintenance program and evaluation of the effects of aging
- No burden on NRC certificate holders since applications for NRC package approval already include both

# Revision of Transitional Arrangements

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 10) (pages 55715–55716)

**Which sections of the CFR would be amended?**

- 10 CFR 71.19

**What are the current and proposed compatibility categories?**

- NRC → NRC

- **Summary:**

- Phase out older packages without a “–85” or “–96” in the package identification number
- Limit use of packages with a “–96” in the package identification number to those whose fabrication has been completed by December 31, 2028
- Limit fabrication of special form sources

- **Additional information:**

- Proposing to revise § 71.19 to allow existing packages be recertified to show compliance with the revised regulations and remove restrictions on package use and fabrication

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# Inclusion of Head Space for Liquid Expansion

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 11) (pages 55716–55717)

**Which sections of the CFR would be amended?**

- 10 CFR 71.43(i)

**What are the current and proposed compatibility categories?**

- [--] → NRC

- **Summary:**

- Would add a design requirement in § 71.43(i) for packages containing liquids to ensure adequate space for liquid expansion during evaluation of the normal conditions of transport and hypothetical accident conditions

- **Additional information:**

- Ensure consistency with § 71.87(d)

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# Deletion of Duplicative Reporting Requirements

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 15.1) (page 55719)

**Which sections of the CFR would be amended?**

- 10 CFR 71.95(a)(3)

**What are the current and proposed compatibility categories?**

- D → [--]

- **Summary:**

- Proposes to remove reporting requirement in § 71.95(a)(3), which is duplicative of paragraph (b)

- **Additional information:**

- None

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## Deletion of References to Irradiated Reactor Fuel in Part 71 Advance Notification Requirements

### Where is this discussed in the FRN?

- Section III.C. (Issue Number 15.1) (page 55720)

### Which sections of the CFR would be amended?

- 10 CFR 71.97

### What are the current and proposed compatibility categories?

- B → B

- **Summary:**

- Would remove references to irradiated reactor fuel in the advance notification requirements in § 71.97

- **Additional information:**

- Advance notice requirements for irradiated reactor fuel are located in 10 CFR Part 73
  - References to irradiated reactor fuel were not removed from § 71.97 when the notifications for small quantities of irradiated reactor fuel were moved to § 73.35

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# Questions and Discussion

# Quality Assurance Program (QAP) Biennial Report Issue

**Where is this discussed in the FRN?**

- Section III.C. (Issue Number 12) (pages 55717)

**Which sections of the CFR would be amended?**

- 10 CFR 71.106

**What are the current and proposed compatibility categories?**

- C → B

- **Summary:**

- Clarification of requirements for biennial reports for QAP changes

- **Additional information:**

- Proposed change modifies language in § 71.106 to clarify that biennial reports are required even when no changes have been made to an NRC-approved QAP in the previous 24-month period
  - Consistent with 10 CFR 50 reporting requirements [§§ 50.54(a)(3) and 50.71(e)(2)]
  - Would match guidance currently provided in RG 7.10
  - Would remove regulatory uncertainty

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# Revision to Agreement State Compatibility Categories

**Where is this discussed in the FRN?**

- Section III.C.(Issue Number 15.4) (pages 55719–55720)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- C → B, §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125
- D → C, §§ 71.95

- **Summary:**

- Regulations that contain QAP review criteria would be revised from Compatibility Category C to Compatibility Category B so Agreement States can approve, inspect, and enforce their licensees' QAPs
- Reporting requirements in § 71.95 would change from Compatibility Category D to Compatibility Category C, so State licensees would report to:
  - NRC for instances of package defects or a reduction in effectiveness
  - State regulator for instances where the CoC was not followed in making a shipment

- **Additional information:**

- §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 would be revised from Compatibility Category NRC to Compatibility Category B
- § 71.95 would be revised from Compatibility Category D to Compatibility Category C

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# Compatibility Categories A and B

**Where is this discussed in the FRN?**

- Section XV. (pages 55725–55727)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- See Compatibility Table

## Compatibility Category A

- Basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts.
- Should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

## Compatibility Category B

- Activities that cross jurisdictional boundaries.
- Need to be adopted in an essentially identical manner in order to ensure uniformity of a regulation on a national basis.

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# Compatibility Category C

**Where is this discussed in the FRN?**

- Section XV. (pages 55725–55727)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- See Compatibility Table

## Compatibility Category C

- Program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.
- Agreement State program elements must embody the essential objectives of these NRC program elements.
- May be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

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# Compatibility Category D

**Where is this discussed in the FRN?**

- Section XV. (pages 55725–55727)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- See Compatibility Table

## Compatibility Category D

- Program elements that do not meet any of the criteria of Compatibility Categories A, B, or C, or have a particular health and safety role.
- Do not need to be adopted by Agreement States for purposes of compatibility.
- An Agreement State may adopt and implement these program elements that fall within its jurisdiction.
- If adopted, the program element should be adopted in a manner such that:
- They are comparable with those of the NRC,
- They do not preclude, or effectively preclude a practice in the national interest without adequate protection of public health and safety, security, or environmental basis related to radiation protection, and
- They do not preclude, or effectively preclude the ability of the NRC to evaluate the effectiveness of the Agreement State program with respect to the protection of public health and safety.

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# Compatibility Categories NRC and H&S

**Where is this discussed in the FRN?**

- Section XV. (pages 55725–55727)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- See Compatibility Table

## Compatibility Category NRC

- Program elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations (CFR).
- The NRC maintains regulatory authority over these program elements.
- Agreement States must not adopt these NRC program elements.

## Compatibility Category H&S

- Program elements that embody the basic health and safety aspects of the NRC's program elements because of particular health and safety considerations.
- Must be adopted by Agreement States.
- Not required for compatibility.

# Compatibility Table: Compatibility Categories and Changes

## Where is this discussed in the FRN?

- Section XV. (pages 55726–55727)

## Which sections of the CFR would be amended?

- N/A

## What are the current and proposed compatibility categories?

- See Compatibility 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<br>[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**  |

| Section                                   | Change                         | Subject  | Compatibility |     |
|---|--------------------------------|--|---------------|-----|
|   |                                |  | Existing      | New |
| 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** |
| 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 <sub>1</sub> and A <sub>2</sub> 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] |

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# Draft Regulatory Guide

**Where is this discussed in the FRN?**

- Section XVII (pages 55727–55728)

**Which sections of the CFR would be amended?**

- N/A

**What are the current and proposed compatibility categories?**

- N/A

- Draft Regulatory Guide DG-7011, “Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material” ([ML22223A085](#))
  - Added detail on air transport requirements in structural and thermal chapters
  - Moved information on materials evaluations to Chapter 7
  - Added Chapter 10 on Quality Assurance
- Unofficial Redline/Strikeout Version of draft guidance (ML22280A061)

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# Questions and Discussion

# Requests for Comments

## Where is this discussed in the FRN?

- Section IV, "Specific Request for Comment," (pages 55720–55722), Section IX, "Cumulative Effects of Regulation," (page 55724)

## IV. Specific Request for Comment:

1. IAEA Changes in SSR–6 (2018 Edition) Not in the Scope of This Proposed Rule
2. Removing Tables A–1 Through A–4 in Appendix A to 10 CFR Part 71
3. Merits of Requiring a Biennial Report for No Changes to a Quality Assurance Program

## IX. Cumulative Effects of Regulation:

1. Does the proposed rule's effective date provide sufficient time to implement the new proposed requirements?
2. If current or projected cumulative effects of regulation challenges exist, what should be done to address this situation?
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.

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# Regulatory Analysis

**Where is this discussed in the FRN?**

- Section VI, “Regulatory Flexibility Certification,” and Section VII, “Regulatory Flexibility Act,” (pages 55723–55724)

- **Summary:**

- The proposed rule represents the best option that could address all the issues and could result in net savings of \$3,354,982 in averted costs to the industry licensees and Certificate of Compliance holders.
- Estimated licensee savings: \$5,929,424.
- Estimated Certificate of Compliance holder costs: (\$2,574,442).
- Net cost to Agreement States: (\$2,408,083) to implement the rule and revise procedures.
  - Implementation costs for the Agreement States: (\$2,242,429).
  - Marginal operational cost for the Agreement States: (\$165,654).

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# Draft Environmental Assessment and Proposed (Draft) Finding of No Significant Impact

## Where is this discussed in the FRN?

- Section XI, "Environmental Assessment and Proposed Finding of No Significant Environmental Impact," (pages 55724)

- **Summary:**

- Alternatives considered:

- Proposed action: rulemaking to amend Part 71
    - No action alternative: do not amend Part 71

- **Impacts:**

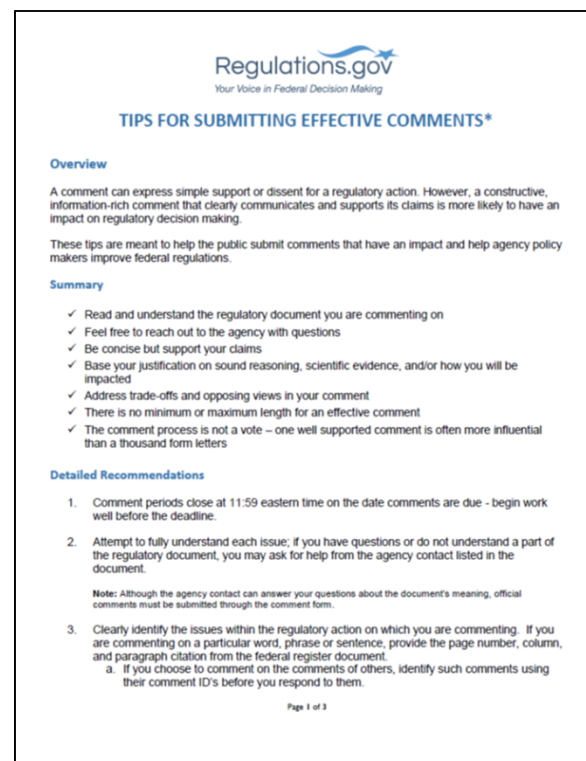
- No significant environmental impacts from the proposed action

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# Resources for Preparing and Submitting Comments

# Commenter's Checklist on Regulations.gov

- Available from [Regulations.gov](https://downloads.regulations.gov/FIS-2018-0053-0007/content.pdf) at:  
<https://downloads.regulations.gov/FIS-2018-0053-0007/content.pdf>
- This information is also available from the page for submitting comments on the proposed rule:  
<https://www.regulations.gov/comment/NRC-2016-0179-0072>



# Submitting a comment

- Frequently Asked Questions (FAQs) on commenting are available at:  
<https://www.regulations.gov/faq>
- **Ways You Can Submit Comments:**
  - **Regulations.gov:** [comment form](#) for the proposed rule on docket NRC–2016–0179
  - or
  - **Email:** [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov)
  - or
  - **Mail:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff

| 55708   |  |
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| Proposed Rules  | Federal Register<br>Vol. 87, No. 175<br>Monday, September 12, 2022 |
| <p>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.</p> <p>• <b>Email comments to:</b><br/><a href="mailto:Rulemaking.Comments@nrc.gov">Rulemaking.Comments@nrc.gov</a>. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.</p> <p>• <b>Mail comments to:</b> Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.</p> <p>For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.</p> <p><b>FOR FURTHER INFORMATION CONTACT:</b><br/>James Firth, 301-415-4628, email: <a href="mailto:James.Firth@nrc.gov">James.Firth@nrc.gov</a>; or Bernard White, 301-415-6577, email: <a href="mailto:Bernard.White@nrc.gov">Bernard.White@nrc.gov</a>. Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.</p> <p><b>SUPPLEMENTARY INFORMATION:</b></p> <p><b>Table of Contents</b></p> <p>I. Obtaining Information and Submitting Comments</p> <p>A. Obtaining Information</p> <p>B. Submitting Comments</p> <p>II. Background</p> <p>III. Discussion</p> <p>A. Action the NRC is Proposing To Take</p> <p>B. Applicability of the Proposed Action</p> <p>C. Discussion of Issues Specific Request for Comment</p> <p>IV. Specific Request for Comment</p> <p>V. Section-by-Section Analysis</p> <p>VI. Regulatory Flexibility Certification</p> <p>VII. Regulatory Analysis</p> <p>VIII. Backfitting and Issue Finality</p> <p>IX. Cumulative Effects of Regulation</p> <p>X. Plain Writing</p> <p>XI. Environmental Assessment and Proposed Finding of No Significant Environmental Impact</p> <p>XII. Paperwork Reduction Act</p> <p>XIII. Criminal Penalties</p> <p>XIV. Coordination with NRC Agreement States</p> <p>XV. Compatibility of Agreement State Regulations</p> <p>XVI. Voluntary Consensus Standards</p> <p>XVII. Availability of Guidance</p> <p>XVIII. Public Meeting</p> <p>XIX. Availability of Documents</p> <p><b>DATES:</b> 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.</p> <p><b>ADDRESSES:</b> You may submit comments by any of the following methods:</p> <ul style="list-style-type: none"><li>• <b>Federal rulemaking website:</b> Go to <a href="https://www.regulations.gov">https://www.regulations.gov</a> and search for Docket ID NRC-2016-0179. Address questions about NRC dockets to Dawn Forder, telephone: 301-415-3407; email: <a href="mailto:Dawn.Forder@nrc.gov">Dawn.Forder@nrc.gov</a>. For technical questions contact the individual or individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.</li><li>• <b>NRC's Agencywide Documents Access and Management System (ADAMS):</b> You may obtain publicly-available documents online in the ADAMS Public Documents collection at <a href="https://www.nrc.gov/reading-rm/adams.html">https://www.nrc.gov/reading-rm/adams.html</a>. 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 <a href="mailto:PDR.Resource@nrc.gov">PDR.Resource@nrc.gov</a>. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.</li><li>• <b>NRC's PDR:</b> You may examine and purchase copies of public documents, by appointment, at the PDR, Room P1 E35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to <a href="mailto:PDR.Resource@nrc.gov">PDR.Resource@nrc.gov</a> 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.</li></ul> <p><b>B. Submitting Comments</b></p> <p>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 <a href="https://www.regulations.gov">https://www.regulations.gov</a> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information that they do not want to be publicly disclosed.</p> |  |

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## Next Steps

- Public comment period ends: November 28, 2022
- Staff will respond to comments and develop a final rule
- Final rule currently due to the Commission: February 2024

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# Questions and Discussion

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# Acronyms

|       |   |      |                                    |
|-------|---|------|------------------------------------|
| ADAMS | Agencywide Documents Access and Management System | IAEA | International Atomic Energy Agency |
| CER   | Cumulative effects of regulation                  | LSA  | Low Specific Activity              |
| CFR   | <i>Code of Federal Regulations</i>                | NRC  | U.S. Nuclear Regulatory Commission |
| CoC   | Certificate of Compliance                         | QAP  | Quality Assurance Program          |
| DG    | Draft regulatory guide                            | QR   | Quick response                     |
| DOT   | U.S. Department of Transportation                 | RG   | regulatory guide                   |
| FAQs  | Frequently Asked Questions                        | SCO  | Surface Contaminated Object        |
| FR    | <i>Federal Register</i>                           | SSR  | Specific Safety Requirements       |
| FRN   | <i>Federal Register</i> notice                    |      |                                    |
| H&S   | Health and safety                                 |      |                                    |