

## **Revisions to Harmonize the Type B and Fissile Material Package Requirements with the Current International Transportation Regulations**

David W. Pstrak, Latif Hamdan, Andrew Barto, Bernard White, and Jeremy Tapp  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission, Washington, DC, USA

### **ABSTRACT**

The U. S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is currently implementing a rulemaking initiative to revise its regulations in Title 10 of the *Code of Federal Regulations*, Part 71 (10 CFR Part 71) for the transportation of radioactive material to harmonize with the 2012 and 2018 editions of the International Atomic Energy Agency's (IAEA's) "Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6" (SSR-6). The NRC and the DOT jointly share responsibility for regulating the transportation of radioactive material. In addition to harmonizing NRC regulations for packaging and transportation of Type B and fissile material, the NRC initiative also includes other staff-initiated administrative, editorial, and clarification changes to improve 10 CFR Part 71 implementation. This paper describes the proposed rulemaking action, including issues of concern, assessments of the rulemaking alternatives, proposed revisions to the existing regulations and regulatory guidance, and potential impacts of the proposed rulemaking on the NRC, certificate holders, licensees, Native American Tribes, and Agreement States. The paper also highlights the public outreach plans that the NRC has exercised as part of the rulemaking process.

### **INTRODUCTION**

The transportation of radioactive material often occurs between and across many nations. Safe transportation of radioactive material is best achieved when there is agreement and alignment of the required packaging and transportation regulations among all the nations involved. In the United States, beginning with the Interstate Commerce Commission and the Atomic Energy Commission [which later became the U.S. Department of Transportation (DOT) and the U.S. Nuclear Regulatory Commission, respectively], there have been periodic revisions to the domestic (i.e., within the United States) transportation regulations for radioactive material to harmonize with the International Atomic Energy Agency (IAEA) transportation regulations. In particular, United States initiated rulemakings in 1966<sup>1</sup>, 1973<sup>2</sup>, 1983<sup>3</sup>, 1995<sup>4</sup>, 2004<sup>5</sup>, and 2015<sup>6</sup>. With an effective date of July 15, 2015, NRC's most recent rule change to 10 CFR Part 71, dated June 12, 2015, the final rule harmonized NRC's regulations in 10 CFR Part 71 with the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1, 2009 edition). The IAEA has since revised and updated its regulations twice for the transportation of radioactive material in "Specific Safety Requirements No. SSR – 6" (SSR-6, 2012 and 2018 edition).

### **BACKGROUND**

Beginning in July 2016, the NRC staff requested approval from the Commission to initiate a rulemaking to harmonize 10 CFR Part 71 with both the IAEA and the DOT regulations and make NRC-initiated changes. Because they co-regulate transportation of radioactive material in the United States, the NRC and DOT have historically coordinated to harmonize their

---

<sup>1</sup> 31 *Federal Register* 9941, July 22, 1966

<sup>2</sup> 38 *Federal Register* 10437, April 27, 1973

<sup>3</sup> 48 *Federal Register* 35600, August 5, 1983

<sup>4</sup> 60 *Federal Register* 50248, September 28, 1995

<sup>5</sup> 69 *Federal Register* 3698, January 26, 2004

<sup>6</sup> 80 *Federal Register* 33987, June 12, 2015

respective regulations with the IAEA revisions through the rulemaking process. The NRC has engaged with DOT on this current rulemaking to identify and evaluate gaps between 10 CFR Part 71 regulations and SSR-6 (2012 and 2018).

In December 2016, NRC and DOT conducted a joint public meeting to discuss NRC’s “issue paper” that identified potential issues for consideration in the rulemaking process. In addition to harmonization issues, the issues paper included consideration of administrative and editorial changes to clarify the regulations. Through this rulemaking process, NRC intends to make recommendations to revise 10 CFR Part 71 to harmonize with the IAEA requirements, ensure compatibility with the DOT regulations, and make administrative and editorial changes or clarifications.

### SCOPE OF THE 10 CFR PART 71 HARMONIZATION

Table 1 lists the harmonization issues and the NRC’s recommended action.

**Table 1 Summary of Regulatory Issues and Recommended Action**

Issue	Description	Relevant Provisions in 10 CFR Part 71	NRC Staff Recommended Action
<b>Issue 1: Fissile Materials</b>	1a - SSR-6 includes three new fissile exceptions in paragraphs 417(c), 417(d), and 417(e).	§ 71.15	Adopt 417(c) exception without the associated consignment limit, do not adopt 417(d), and adopt 417(e) exceptions with modifications.
	1b – SSR-6 includes a “Competent Authority <sup>7</sup> -approved” fissile exception in paragraph 417(f).	§ 71.15	Do not adopt.
	1c - SSR-6 includes provisions in SSR-6 paragraph 674 for CSI-controlled packages of fissile material, similar to the fissile material general license requirements in 10 CFR Part 71.	§ 71.22 § 71.23	Do not adopt.
	1d - SSR-6 includes provisions in paragraph 675 for plutonium in non-fissile packages, similar to the fissile exemption in 10 CFR 71.15(f), but with accumulation control.	§ 71.15	Do not adopt.
<b>Issue 2: Reduced External Pressure Requirement</b>	SSR-6 and DOT (49 CFR 173.412(f)) reduced external pressure value is 60 kPa (8.7 psia).	§ 71.71(c)(3)	Adopt.

<sup>7</sup> A competent authority is the national entity that imposes IAEA regulations. In the U.S., the U.S. Department of Transportation is the U.S. competent authority.

Issue	Description	Relevant Provisions in 10 CFR Part 71	NRC Staff Recommended Action
<b>Issue 3: Type C Package Standards</b>	SSR-6 has Type C package standards.	None	Do not adopt.
<b>Issue 4: Solar Insolation</b>	4a - SSR-6 unit for solar insolation differs from NRC.	§ 71.71(c)(1)	Adopt.
	4b - SSR-6 require solar insolation as an initial condition for the tests.	§ 71.73 (b)	Adopt.
<b>Issue 5: Radiation Level versus Dose Equivalent Rate</b>	SSR-6 changed the term “radiation level” to “dose equivalent rate”.	§ 71.4 § 71.43 § 71.47 § 71.51 § 71.64 § 71.87	Do not adopt.
<b>Issue 6: Deletion of Low Specific Activity-III Leaching Test</b>	SSR-6 removed the leaching test requirement for LSA-III material.	§ 71.4 § 71.77 § 71.100	Adopt.
<b>Issue 7: Large Surface Contaminated Objects (SCO-III)</b>	SSR-6 added provisions for large surface contaminated objects under a new SCO-III category.	§ 71.4	Add a definition of SCO-III, if the DOT adds it to its regulations.
<b>Issue 8: UF<sub>6</sub> Cylinder Plugs</b>	In SSR-6 paragraph 680(b)(i) added evaluation of the cylinder plug for uranium hexafluoride (UF <sub>6</sub> ).	§ 71.55(g)	Adopt.
<b>Issue 9: Aging Management</b>	SSR-6 adds evaluation of aging mechanisms and requirements for transport after storage	§ 71.35 § 71.43(d)	Adopt.
<b>Issue 10: Transitional Arrangements</b>	SSR-6 revises transitional arrangements for package designs and special form radioactive material.	§ 71.4 § 71.19	Adopt.
<b>Issue 11: Head Space for Liquid Expansion</b>	The regulation lacks a general design requirement to ensure that packages containing liquid have sufficient head space.	§ 71.43	Adopt.

Issue	Description	Relevant Provisions in 10 CFR Part 71	NRC Staff Recommended Action
<b>Issue 12: Quality Assurance Program Biennial Report</b>	Current regulations do not require quality assurance program (QAP) approval holders to submit a biennial report to the NRC if no changes were made to the QAP in the 24-months previous, however, the associated SOCs and RG 7.10 discuss submitting the biennial report even if no changes were made.	§ 71.106(b)	Adopt.
<b>Issue 13: Type A Package requirements in Fissile Material General Licenses</b>	The mass limits in the fissile material general licenses in 10 CFR Part 71 are not consistent with the Type A restriction for some fissile nuclides.	§ 71.22 § 71.23	Adopt.
<b>Issue 14: <sup>233</sup>U Restriction in 10 CFR 71.22 – General License: Fissile Material</b>	The fissile material general license in 10 CFR 71.22 contains lower mass limits for <sup>235</sup> U if <sup>233</sup> U is “present” in the package. It is not clear what concentration of <sup>233</sup> U constitutes being “present.”	§ 71.22	Adopt.
<b>Issue 15: Other Recommended Changes to 10 CFR Part 71</b>	15a - Regulations have duplicative reporting requirements	§ 71.95(b)	Adopt.
	15b - An error exists in the definition of LSA material.	§ 71.4	Adopt.
	15c - SSR-6 revised some A <sub>1</sub> and A <sub>2</sub> values; exempt material activity concentrations; and exempt consignments activity limits.	10 CFR Part 71 Appendix A Tables A-1 and A-2	Adopt.
	15d - The compatibility category for the regulations containing QAP review criteria for Agreement State review, approval, and inspection of the use of Type B packages, other than industrial radiography use, are Compatibility Category NRC.	§ 71.109 * § 71.111 § 71.115 § 71.117 § 71.119 § 71.121 § 71.123 § 71.125	Adopt.

\*Although the NRC lists the 10 CFR Part 71 sections that contain QAP criteria, the NRC is not proposing to make any change to the content of these sections at this time. The NRC includes them in Table 1 as a reference to those QAP-related sections that the NRC is considering for Agreement State compatibility.

The staff considered and evaluated the following four alternatives for each issue:

- Alternative 1: No-Action Alternative
- Alternative 2: Issue Generic Communications and Revise Regulatory Guidance
- Alternative 3: Issue License-Specific Conditions and Exemptions
- Alternative 4: Revise 10 CFR Part 71

Alternatives 1 and 4 were included in the rulemaking plan that was provided to the Commission, and Alternatives 3 and 4 are additional alternatives identified during the staff's assessment of the regulatory issues.

### **Alternative 1: No-Action Alternative**

Alternative 1 maintains the status quo, and the NRC would undertake no action and make no changes to the current regulations in 10 CFR Part 71 or supporting regulatory guidance documents. Alternative 1 is the staff's recommended action for Issues 3 and 5.

Implementing this alternative for all the issues would not be consistent with the NRC's past response to revisions and updates of the IAEA regulations, which has included rulemakings to harmonize 10 CFR Part 71 with the IAEA regulations. The no-action alternative will result in inconsistencies and differences between the NRC's regulations and the IAEA's regulations, as well as the DOT's regulations should the DOT decide to revise its regulations independent of the NRC. Such inconsistencies and differences can cause uncertainty and difficulties given conflict or duplication across requirements and negative impacts on both existing and new certificate holders and licensees. As the IAEA has periodically changed its requirements and standards to take advantage of increased knowledge and industry experience, without this proposed harmonization, 10 CFR Part 71 regulations would continue to diverge from the international regulations. A decision not to harmonize at this time may make harmonization of the NRC regulations with the international regulations (and possibly DOT regulations) increasingly difficult over time.

### **Alternative 2: Issue Generic Communications and Revise Regulatory Guidance**

Under this alternative, the NRC would use generic communications (Regulatory Issue Summaries, Generic Letters, or Bulletins) to inform existing certificate holders and licensees of its endorsement or other positions regarding the latest IAEA regulations and safety requirement updates in SSR-6, 2012 and 2018 editions. No further resources or costs would be incurred for performing a rulemaking action; however, some regulatory guidance documents would have to be revised and some revisions would need to be coordinated with the DOT.

Alternative 2 is not part of the staff's recommended action for any of the issues. This alternative is not consistent with the NRC's past response to revisions and updates of the IAEA regulations, which has included rulemaking to harmonize 10 CFR Part 71 with the IAEA's regulations. Guidance documents and generic communications do not change existing regulations and are not suitable for addressing some of the regulatory issues identified by the staff. Furthermore, if this alternative is adopted, inconsistencies and differences would remain between the NRC's regulations and the IAEA's regulations, and between NRC's regulations and DOT's regulations should the DOT decide to harmonize its regulations with the IAEA regulations independent of the NRC.

### **Alternative 3: Issue License-Specific Conditions and Exemptions**

Under this alternative, individual licensees can request exemptions from the NRC's regulations for consistency with the revised IAEA regulations. This alternative differs from

the no-action alternative (Alternative 1) only in that it could have increased licensee requests for exemptions and greater regulatory burden and costs to licensees and NRC. This alternative is not consistent with the NRC's past response to revisions and updates of the IAEA's regulations, which has included rulemaking to harmonize 10 CFR Part 71 with the IAEA's regulations.

Alternative 3 is not part of the staff's recommended action. If this alternative is selected, the NRC's regulations in 10 CFR Part 71 will continue to be inconsistent with the IAEA's requirements and some DOT regulations, and licensees and NRC would incur operational costs that would not be incurred if 10 CFR Part 71 is revised.

In addition, license-specific conditions and exemptions are not suitable for addressing some of the complex issues identified by the staff. However, NRC will continue to review submitted exemption requests, on a case by case basis, in accordance with 10 CFR Part 71.

#### **Alternative 4: Revise 10 CFR Part 71**

This alternative is the action recommended by the staff for all the issues, except for Issues 3 and 5.

Overall, the staff has determined that Alternative 4 is the best approach to harmonize the NRC's regulations in 10 CFR Part 71 with the 2012 and 2018 editions of SSR-6, and to ensure that the NRC's regulations continue to be compatible with the DOT's regulations. The proposed rule would also include staff-initiated administrative, editorial, or clarification changes covered in the issues paper (Issues 11, 12, 13, and 14), as well as other items that were identified by the staff after that paper was issued (reporting requirements, LSA definition, Tables A-1 and A-2 in Appendix A to 10 CFR Part 71, and the compatibility category for the regulations containing QAP review criteria for Agreement State review) that are discussed under Issue 15. Finally, the proposed action would also involve making conforming changes to existing regulatory guidance.

#### **Viability of Issue Resolution by Different Alternatives**

Table 2 provides a list of the issues and the viability of issue resolution by different alternatives. Some issues require a rule change and cannot be resolved by guidance, and cost-prohibitive alternatives were not considered viable to achieve the regulatory objective.

**Table 2 Viability of Issue Resolution by Alternative**

Issues	Alternatives			
	1	2	3	4
Issue 1: Fissile Materials			✓	✓
Issue 2: Reduced External Pressure			✓	✓
Issue 3: Type C Package Standards	✓			
Issue 4: Solar Insolation		✓		✓
Issue 5: Radiation Level versus Dose Equivalent Rate	✓			✓
Issue 6: Deletion of Low Specific Activity-III Leaching Test			✓	✓
Issue 7: Large Surface Contaminated Objects (SCO-III)			✓	✓

Issues	Alternatives			
	1	2	3	4
Issue 8: UF <sub>6</sub> Cylinder Plugs		✓		✓
Issue 9: Aging Management		✓		✓
Issue 10: Transitional Arrangements			✓	✓
Issue 11: Head Space for Liquid Expansion		✓		✓
Issue 12: Quality Assurance Program Biennial Report		✓		✓
Issue 13: Type A Package Requirements in Fissile Material General Licenses			✓	✓
Issue 14: <sup>233</sup> U Restriction in 10 CFR 71.22 – General License: Fissile Material		✓		✓
Issue 15: Other Recommended Changes to 10 CFR Part 71	✓			✓
Number of Issues that Could Be Addressed by Corresponding Alternative	3	6	6	14

### Alternatives Summary and Conclusions

Based on the above evaluations, the staff has reached the following conclusions:

1. The rulemaking option (Alternative 4), in combination with the no-action alternative (Alternative 1) for Issues 3 and 5, would address and resolve all the regulatory issues identified by the staff and accomplish the goals of the harmonization initiative:
  - Resolution of Issues 1, 4, 6, 7, 8, 9, and 10 by a rulemaking action would harmonize the NRC'S existing regulations with the current IAEA regulations in SSR-6, 2012 and 2018 editions.
  - Resolution of Issues 2 and 15 (in part) by a rulemaking action would maintain compatibility between the NRC's regulations in 10 CFR Part 71 and DOT's regulations in 49 CFR Parts 107 and 171-180.
  - Resolution of Issues 11, 12, 13, 14, and 15 (in part) by a rulemaking action would clarify 10 CFR Part 71.
2. The staff-recommended rulemaking would reduce the regulatory burden on licensees and certificate holders by maintaining consistency between NRC and DOT regulations and alignment with IAEA requirements, and thereby eliminate conflicting requirements.
3. The rulemaking action recommended by the staff is consistent with the NRC's response to earlier revisions and updates of the international regulations by the IAEA. The staff recommended action represents the least costly viable option and would result in savings to the industry; alternatives 2 and 3 would not address all the regulatory issues identified by staff and would also result in higher costs to the NRC, certificate holders, and licensees.

On April 30, 2019, the NRC conducted a public meeting at its Headquarters office in Rockville, MD, to present the Regulatory Basis for each issue. The technical staff who did the research and developed the recommendations provided a presentation on each issue. Participants asked questions, and there was an exchange of information. NRC reminded the participants that the comment period for this step in the rulemaking process began April 12, 2019, and will end May 28, 2019. Many steps remain for the overall rulemaking process for

adoption of these 15 issues, and NRC currently estimates the final rule will be published in the Federal Register in early 2022.

NRC encourages stakeholders, Native American Tribes, and Agreement States to participate in future public meetings and make comments during comment periods. Such participation and input will assist the NRC to better understand the impacts of these issues.

Overall, as the rulemaking process continues, certificate holders, licensees, and the Agreement States will need to assess the potential impacts on their individual programs. NRC does not anticipate an impact to Native American Tribes as a result of changes described by this harmonization effort, as the Tribes do not approve transportation packages nor do they have Quality Assurance Programs for package qualification or use.

### **SUMMARY**

The NRC is considering to revise its regulations in 10 CFR Part 71 to harmonize with the IAEA's standards found in SSR-6 (2012 and 2018 editions). Through the rulemaking process, NRC intends to make recommendations to revise 10 CFR Part 71 to harmonize with the IAEA requirements, ensure compatibility with the DOT regulations, and make administrative and editorial changes or clarifications. The NRC and DOT share responsibility for regulating the packaging and transportation of radioactive material in the United States, therefore, the NRC and DOT will work together to ensure compliance between each agency's respective requirements. The NRC will seek input during comment periods and will conduct public meetings associated with the rulemaking process.