

# PUBLIC SUBMISSION

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**Docket:** NRC-2016-0179

Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Requirements

**Comment On:** NRC-2016-0179-0078

Harmonization of Transportation Safety Requirements with IAEA Standards; Correction

**Document:** NRC-2016-0179-DRAFT-0086

Comment on FR Doc # 2022-22866

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## Submitter Information

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**Organization:** Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR)

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## General Comment

Council on Radionuclides and Radiopharmaceutical, Inc (CORAR) comments regarding Docket ID NRC-2016-0179 enclosed.

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## Attachments

CORAR Final Comments to NRC (11-28-22) - re Harmonization with IAEA Revised



*The Council on Radionuclides and Radiopharmaceuticals, Inc.*

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**November 28, 2022**

U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, Maryland 20852.

**RE: DOCKET ID NRC-2016-0179, HARMONIZATION OF TRANSPORTATION SAFETY  
REQUIREMENTS WITH IAEA STANDARDS; CORRECTION; FEDERAL REGISTER  
VOL. 87, NO. 208; OCTOBER 28, 2022**

I am writing today on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to provide comments regarding the regulatory basis to amend the U.S. Nuclear Regulatory Commission (NRC)'s regulations, in consultation with the U.S. Department of Transportation (DOT), for the packaging and transportation of radioactive materials to ensure harmonization with the International Atomic Energy Agency standards published in the *Federal Register*, Vol. 87, No. 208, published on October 28, 2022. CORAR is an industry association of firms that manufacture diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine, research, and industry. Also, CORAR members include firms that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities.

The national responsibility to establish and enforce standards for the safe handling and transport of radioactive materials within the United States rests with the DOT and the NRC. However, given the international supply chain for radiopharmaceuticals, medical radioisotopes, industrial radioisotopes, and sealed sources, the need to ensure the safe transport of these materials transcends national borders and requires international cooperation. With that said, CORAR member companies recognize the importance of harmonizing NRC regulations with the International Atomic Energy Agency (IAEA) to promote the safe transport of radioactive materials and we appreciate the opportunity to comment on the proposed rule.

Please do not hesitate to contact me at (202) 547-6582 if you have questions or need additional information regarding our comments.

Respectfully,

A handwritten signature in blue ink, reading 'Michael J. Guastella', with a stylized flourish extending to the right.

Michael J. Guastella  
Executive Director

**Council on Radionuclides and Radiopharmaceuticals, Inc.**

**HARMONIZATION OF TRANSPORTATION SAFETY REQUIREMENTS WITH IAEA STANDARDS; CORRECTION; FEDERAL REGISTER VOL. 87, NO. 208; OCTOBER 28, 2022**

**CORAR member responses to Section IV. Specific Request for Comments are provided below:**

- 1. QUESTION 1: 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.**

CORAR members' response to this question is Yes, and CORAR members request that §71.70 (b)(2) be revised to reference ISO 2919:2012 instead of ISO 2919:1999, consistent with SSR-6 2018.

In addition, consideration should be given to updating the reference in §71.70 (b)(1) from ISO 9978:1992 to ISO 9978:2020.

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

CORAR members believe that including these tables in CFR 71 is redundant. Therefore, CORAR supports removing Tables A-1 through A-4, and replacing these with a reference to the appropriate DOT Tables in 49 CFR chapter I.

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

CORAR members do not believe there is any benefit in requiring a QAP holder to submit a biennial report indicating that there have not been any changes to the QAP during the reporting period. The QAP is available to the NRC during licensee inspections. If the licensee does not provide a biennial report on minor changes to the QAP, then this should be indicative that there have not been any revisions to the QAP.

**CORAR comments to Section III., C. Discussion of Issues 1 through 15 are provided below:**

- 4. Issue 1: Revision of Fissile Exemption:**

CORAR members offer no comments.

- 5. Issue 2: Revision of Reduced External Pressure Test for Normal Conditions of Transport:**

CORAR members support NRC's decision not to further pursue any changes to the reduced external pressure test requirement under 10 CFR Part 71.71(c)(3).

- 6. Issue 3. Inclusion of Type C Package Standards:**



CORAR members support NRC's decision to not further pursue any changes to 10 CFR Part 71 to adopt Type C package standards.

**7. Issue 4.1: Unit of Measure for Insolation for Normal Conditions of Transport:**

CORAR members support revising the units of measure for insolation and concur with NRC's conclusion that certificate holders should be able to demonstrate compliance package approval standards given the small increase ( $\approx 3.3\%$ ) in insolation due to the revised units.

**8. Issue 4.2: Inclusion of Insolation for Hypothetical Accident Conditions:**

CORAR members support revising §71.73 to include insolation as an initial condition for the thermal test, consistent with para. 728 of SSR-6. However, as the rule is written, the initial condition of insolation would apply to the free drop, crush and puncture tests.

The rule as proposed would unnecessarily complicate the development of applications to approve - 96 Type B(U) packages against the new rules as well as complicating the approval to use foreign packages that may have been designed and tested in accordance with SSR-6.

To be consistent with SSR-6, we suggest that the initial condition of insolation is included in §71.73(c)(4) and that no change is made to §71.73 (b) as follows, "§71.73(c) (4) Thermal. Exposure of the specimen, in thermal equilibrium at an ambient temperature of +38 °C (+100 °F) and with insolation 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, fully engulfed..."

**9. Issue 5: Inclusion of Definition for Radiation Level:**

CORAR members support defining the term Radiation Level in §71.4.

**10. Issue 6: Deletion of the Low Specific Activity-III Leaching Test:**

CORAR members offer no comments.

**11. Issue 7: Inclusion of New Definition for Surface Contaminated Object (SCO-III):**

CORAR members support the NRC proposal to harmonize 10 CFR Part 71 with SSR-6 and DOT regulations by adding the definition of SCO-III to 10 CFR 71.4.

**12. Issue 8: Revision of Uranium Hexafluoride Package Requirements:**

CORAR members offer no comments.

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

CORAR members agree with the NRC's revisions to §§71.31, 71.35, and 71.43 to incorporate the consideration of aging mechanisms. CORAR members also concur with the view that aging mechanisms, while to specifically cited, are already reviewed as part of a package approval, and that these revisions are consistent with SSR-6.

**14. Issue 10: Revision of Transitional Arrangements:**

CORAR members believe that the harmonization of regulations pertaining to the transportation of radioactive material is crucial to ensuring sealed radioactive sources (as well as other forms of

radioactive material) are transported safely and consistently around the world. Also, CORAR members agree with the proposed revisions to §§71.17 and 71.19 to incorporate transitional arrangements.

**CORAR members request that the NRC recognize the impact the transitional arrangements will have on the -96 Type B(U) packages and the period of time from when a final rule is published and the December 31, 2025 date that would require multilateral approval for shipments to locations outside of the US.**

**In addition, CORAR members recommend that the NRC develop guidance for certificate holders who wish to resubmit applications to meet the revised standards, considering the minimal changes between the current and revised package performance and evaluation criteria.**

**15. Issue 11: Inclusion of Head Space for Liquid Expansion:**

CORAR members agree with the NRC's proposal to add a design requirement to ensure that package components that contain liquid have sufficient head space for liquid expansion under the tests for normal conditions of transport and hypothetical accident conditions.

**16. Issue 12: Revision of Quality Assurance Program Biennial Reporting Requirements:**

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. CORAR members do not believe there is any benefit to require a biennial report indicating that there have been no changes to the QAP and request that NRC not finalize this clarification to § 71.106(b).

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

CORAR members offer no comments.

**18. Issue 14: Deletion of 233U Restriction in Fissile General License:**

CORAR members offer no comments.

**19. Issue 15.1: Delete Duplicative Reporting Requirements in 10 CFR 71.95:**

CORAR members offer no comments.

**20. Issue 15.2: Revise the Definition of LSA in 10 CFR 71.4:**

CORAR members offer no comments.

**21. Issue 15.3: Revise the A1 and A2 Values and the Exempt Material Activity Concentrations and Exempt Consignment Activity Limits:**

CORAR members concur with the NRC's proposed revisions to Tables A-1 and A-2 in Appendix A to 10 CFR Part 71 to add seven radionuclides (135mBa, 69Ge, 193mIr, 57Ni, 83Sr, 149Tb and 161Tb), however we also believe that these tables are duplicative of the tables in 49 CFR §173.435 and could be removed from Part 71.

**22. Issue 15.4: Revision to Agreement State Compatibility Categories:**

CORAR members offer no comments pertaining to Issue 15.4 and believe that the decision to revise 10 CFR 71 or select a No-Action Alternative is best left to the Agreement States and NRC.

**23. Issue 15.5: Address Redundancies in Advance Notification Requirements of 10 CFR 71.97 with Requirements of 10 CFR Parts 37 and 73:**

CORAR members offer no comments.