



INTERNATIONAL SOURCE SUPPLIERS
AND PRODUCERS ASSOCIATION

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SAFE AND SECURE AT THE SOURCE



November 8, 2022

Secretary
U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001,
ATTN: Rulemakings and Adjudications Staff
Rulemaking.Comments@nrc.gov

Subject: Comments to Proposed Rule
Harmonization of Transportation Safety Requirements With IAEA
Standards
Docket ID NRC-2016-0179

Dear Secretary,

The International Source Suppliers and Producers Association (ISSPA) is a non-profit trade association comprised of 18 companies located in 8 countries that produce, manufacture, and supply sealed radioactive sources and/or equipment containing radioactive sources as an integral component of the device.

The mission of ISSPA is to ensure that the beneficial use of radioactive sources continues to be regarded as a safe, secure, viable technology for medical, industrial, and research applications. Member companies strive for continuous improvements in the safe and secure use, transport and end of life management of sealed radioactive sources.

ISSPA member companies recognize the importance harmonized regulations for the transportation of radioactive material has on our ability to safely deliver our products to customers and we appreciate the opportunity to comment on the proposed rule.

Please find our comments attached to this letter.

Sincerely,

John J. Miller, CHP
Chairman, ISSPA

| Specific Request for Comment | Comment |
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| <p>QUESTION 1: IAEA Changes in SSR-6 (2018 Edition) Not in the Scope of This Proposed Rule.</p> <p>Is there anything in SSR-6, 2018 Edition, that the NRC did not include in the scope of this proposed rule, but should have?</p> | <p>Yes, §71.70 (b)(2) should be revised to reference ISO 2919:2012 instead of ISO 2919:1999, consistent with SSR-6 2018.</p> <p>Consideration should be given to updating the reference in §71.70 (b)(1) from ISO 9978:1992 to ISO 9978:2020.</p> |
| <p>QUESTION 2: Removing Tables A-1 Through A-4 in Appendix A to 10 CFR Part 71.</p> <p>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.</p> | <p>We support removing Tables A-1 through A-4, and replacing these with a reference to the appropriate DOT Tables in 49 CFR chapter I.</p> <p>Including these tables in CFR 71 is redundant.</p> |
| <p>QUESTION 3: Merits of Requiring a Biennial Report for No Changes to a QAP.</p> <p>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.</p> | <p>We 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.</p> |

| Comments to Issues 1 through 15 | |
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| Issue 1: | <i>Revision of Fissile Exemptions</i> |
| | ISSPA has no comments pertaining to Issue 1. |
| Issue 2: | <i>Revision of Reduced External Pressure Test for Normal Conditions of Transport</i> |
| | ISSPA supports NRCs decision not to further pursue any changes to the reduced external pressure test requirement under 10 CFR Part 71.71(c)(3). |
| Issue 3: | <i>Type C Package Standards</i> |
| | ISSPA supports NRCs decision not to further pursue any changes to 10 CFR Part 71 to adopt Type C package standards |
| Issue 4.1 | <i>Unit of Measure for Insolation for Normal Conditions of Transport</i> |
| | ISSPA supports revising the units of measure for insolation and concurs with NRCs 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. |
| Issue 4.2 | <i>Inclusion of Insolation for Hypothetical Accident Conditions</i> |
| | <p>ISSPA supports 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.</p> <p>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.</p> <p>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).</p> <p>§71.73(c) (4) Thermal. Exposure of the specimen, <u>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,</u>...</p> |
| Issue 5: | <i>Inclusion of Definition for Radiation Level</i> |
| | ISSPA supports defining the term Radiation Level in §71.4. |
| Issue 6: | <i>Deletion of the Low Specific Activity-III Leaching Test</i> |
| | ISSPA has no comments pertaining to Issue 6. |

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| Issue 7: | <i>Inclusion of New Definition for Surface Contaminated Object (SCO-III)</i> |
| | ISSPA supports 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. |
| Issue 8: | <i>Revision of Uranium Hexafluoride Package Requirements</i> |
| | ISSPA has no comments pertaining to Issue 8. |
| Issue 9: | <i>Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program</i> |
| | ISSPA concurs with the NRC's revisions to §§71.31, 71.35, and 71.43 to incorporate the consideration of ageing mechanisms. ISSPA also concurs with the view that ageing mechanisms, while to specifically cited, are already reviewed as part of a package approval, and that these revisions are consistent with SSR-6. |
| Issue 10: | <i>Transitional Arrangements</i> |
| | ISSPA member companies believe that the harmonization of regulations pertaining to the transportation of radioactive material is crucial in ensuring sealed radioactive sources as well as other forms of radioactive material are transported safely and consistently around the world and concur with the proposed revisions to §§71.17 and 71.19 to incorporate transitional arrangements. We would ask the NRC to 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, and consider developing 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. |
| Issue 11: | <i>Inclusion of Head Space for Liquid Expansion</i> |
| | ISSPA concurs with 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. |
| Issue 12: | <i>Revision of Quality Assurance Program Biennial Reporting Requirements</i> |
| | ISSPA does not believe there is any benefit to require a biennial report indicated that there have been no changes to the QAP. |
| Issue 13: | <i>Deletion of Type A Package Limitations in Fissile Material General Licenses</i> |
| | ISSPA has no comments pertaining to Issue 13. |
| Issue 14: | <i>Deletion of 233U Restriction in Fissile General License</i> |
| | ISSPA has no comments pertaining to Issue 14. |



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| Issue 15.1: | <i>Delete Duplicative Reporting Requirements in 10 CFR 71.95</i> |
| | ISSPA has no comments pertaining to Issue 15.1. |
| Issue 15.2: | <i>Revise the Definition of LSA in 10 CFR 71.4</i> |
| | ISSPA has no comments pertaining to Issue 15.2. |
| Issue 15.3: | <i>Revise the A1 and A2 Values and the Exempt Material Activity Concentrations and Exempt Consignment Activity Limits</i> |
| | ISSPA concurs 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 (^{135m} Ba, ⁶⁹ Ge, ^{193m} Ir, ⁵⁷ Ni, ⁸³ Sr, ¹⁴⁹ Tb and ¹⁶¹ Tb), however we also believe that these tables are duplicative of the tables in 49 CFR §173.435 and could be removed from Part 71. |
| Issue 15.4: | <i>Revision to Agreement State Compatibility Categories</i> |
| | ISSPA has 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. |
| Issue 15.5: | <i>Address Redundancies in Advance Notification Requirements of 10 CFR 71.97 with Requirements of 10 CFR Parts 37 and 73.</i> |
| | ISSPA has no comments pertaining to Issue 15.5. |