



Cardinal Health

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 Cardinal Health, Nuclear & Precision Health Solutions (NPHS) 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. NPHS is a radiopharmaceutical manufacturer and distributor through over 130 nuclear pharmacies and 30 PET manufacturing sites in 45 states and Puerto Rico. We dispense and deliver in excess of 12 million doses to patients nationwide for diagnostic and therapeutic purposes.

The NRC and the DOT are responsible to establish and enforce standards for the safe handling and transport of radioactive materials within the United States. Many companies working with radioactive material for medical purposes have been struggling to maintain adequate supply chains for needed isotopes.

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, NPHS recognizes 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 (614)757-9586 if you have questions or need additional information regarding our comments.

Sincerely,

Glenn P. Sullivan, Ph.D.
Director, Health Physics
Corporate Radiation Safety Officer
Cardinal Health Nuclear & Precision Health Solutions

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

NPBS 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.**

NPBS' response to this question is Yes, and NPBS requests 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.**

NPBS believes that including these tables in CFR 71 is redundant. Therefore, NPBS 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.**

NPBS does 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.

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

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

NPBS offers no comments.

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

NPBS supports 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:**

NPHS supports 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:

NPHS supports 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:

NPHS 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.

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

NPHS supports defining the term Radiation Level in §71.4.

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

NPHS offers no comments.

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

NPHS supports 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:

NPHS offers no comments.

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

NPHS agrees with the NRC's revisions to §§71.31, 71.35, and 71.43 to incorporate the consideration of aging mechanisms. ISSPA also concurs 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:

NPHS believes 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, NPHS agrees with the proposed revisions to §§71.17 and 71.19 to incorporate transitional arrangements.

NPHS requests 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, NPHS recommends 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:

NPBS agrees 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. NPBS does 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:

NPBS offers no comments.

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

NPBS offers no comments.

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

NPBS offers no comments.

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

NPBS offers no comments.

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

NPBS 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 (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:

NPBS offers 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:

NPBS members offer no comments.

From: [Sullivan, Glenn](#)
To: [RulemakingComments Resource](#)
Cc: [James Firth](#); [Bernie White](#)
Subject: [External_Sender] NRC and DOT harmonization
Date: Tuesday, November 22, 2022 2:35:06 PM
Attachments: [image002.png](#)
[CAH Comments to NRC and DOT harmonization 221122.pdf](#)

Good afternoon gentlemen. I wanted to thank you for your time and presentation concerning the harmonization of the NRC and DOT requirements.

This is a great opportunity to change the regulations and minimize duplicity and provide a better understanding of how the regulations affect our company. As I made you aware, we transport over 20,000 Type A packages on a daily basis, driving them over 10 million miles to patients in need of care. If you have any questions, please do not hesitate to contact me at the information below.

Thanks
g



Glenn P. Sullivan, Ph.D.

*Director Health Physics /Corporate
Radiation Safety Officer/Quality
Compliance*

Nuclear & Precision Health Solutions

7000 Cardinal Place
Dublin, OH 43017
614/757-9586 tel

I am *Essential to care*

Restorative, Learner, Achiever, Individualization, Harmony

ISFJ (The Defender).

This message is for the designated recipient only and may contain privileged, proprietary or otherwise private information. If you have received it in error, please notify the sender immediately and delete the original. Any other use of the email by you is prohibited.

Dansk - Deutsch - Espanol - Francais - Italiano - Japanese - Nederlands - Norsk - Portuguese - Chinese

Svenska: <http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html>