



26

Council on Radionuclides and Radiopharmaceuticals, Inc.

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~~DOCKET NUMBER~~
~~PROPOSED RULE~~
(67FR 21390)

DOCKETED
USNRC

July 29, 2002 (5:27PM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Henry H. Kramer, Ph.D., FACNP
Executive Director

July 26, 2002

Secretary,
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Rulemaking and Adjudications Staff

**RE: Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other
Transportation Safety Amendments**

**RIN 3150-AG71
Federal Register 21390, April 30, 2002.**

Gentlemen:

These comments concerning NRC's proposed adoption of TS-R-1 in 10CFR71 are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include shippers and carriers of diagnostic and therapeutic radiopharmaceuticals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

GENERAL COMMENTS

CORAR understands the need for harmonization with the international requirements for the transportation of radioactive material. We appreciate the efforts of the NRC to adopt the requirements of TS-R-1 into Part 71, and applaud the NRC for working in cooperation with the DOT to ensure that any changes to the regulations of these agencies will be consistent, concurrent, cost effective, and improve safety and security.

Harmonization enhances the ability of shippers and carriers of import and export shipments to conduct business in compliance with all regulations. At the same time, the adoption of new or modified requirements into the domestic regulations for transportation of radioactive materials must be justified in terms of cost and the need for improved safety and performance. The need

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for changes and additional technical complexity of the regulations such as the nuclide specific thresholds is not warranted based on the history of performance in the transportation of radioactive materials. The established safety and performance record of transportation of radiopharmaceuticals to accommodate 14 million medical tests each year has demonstrated that existing controls are effective.

While we understand, especially those of us who ship internationally, the intent of the NRC to achieve harmonization with international transportation requirements, the current process used by domestic agencies to retrofit or otherwise adopt IAEA requirements in an inconsistent timeline needs to be changed. The timeliness of this process needs to be improved. Moreover, the two year cycle at which changes are now being transacted by IAEA in cooperation with the competent authorities is needlessly frequent, resulting in demands on the resources of both the competent authorities and the regulated community to adopt to changes that are unwarranted as they provide little value to a segment of transportation that, based on its track record, requires no improvement.

SPECIFIC COMMENTS ON THE ISSUES CONSIDERED IN THE PROPOSED RULE

1. Revisions of A_1 and A_2

The scientific basis for the changes to the A_1/A_2 values is understood and justified. However, we agree with the provision in Table A-1 of Appendix A to Part 71 to maintain the exception to allow domestic Type A_2 limit of 20 Ci for Mo-99 and appreciate NRC's understanding of the justification for this. This is needed to allow domestic manufacturers to continue to provide Mo-99 generators to the diagnostic nuclear medicine community. A change in the A_2 limit to the value in TS-R-1 would result in an increase in the number of packages ship and, therefore, and increase in the doses received by manufacturers, carriers and end users. Contamination Control

2. Type C Packages and Low Dispersible Material

We support NRC's proposal to not adopt the requirements for Type C packages and Low Dispersible Material. The IAEA requirement considered additional performance criteria that reflect those in the NRC requirements in 10CFR71.64 and 71.74 for air shipments of plutonium. In the course of IAEA revision, these requirements evolved into the Type C package requirements and were expanded to include all radionuclides. While most member states took the position that these requirements would only impact a few shipments other than plutonium, the impact would be significant on radionuclides such as Co-60. The need nor the benefit have been demonstrated for these requirements and therefore the cost cannot be justified.

3. Grandfathering Previously Approved Packages

CORAR supports the proposal to accept the IAEA transitional requirements including the phase out of Type B specification packages and the termination of authorization of Safety Series 6 (1967) packages. Specification packages and Safety Series 6 (1967) packages have not been designed and constructed according to standards where their continued use would be consistent with the intent of the regulations.

CORAR appreciates the opportunity to provide the NRC with comments on the proposed adoption of TS-R-1. If you should have any questions or need additional information concerning these comments, please feel free to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark A. Doruff". The signature is written in a cursive style with a large initial "M" and a long, sweeping underline.

Mark A. Doruff
Council on Radionuclides and Radiopharmaceuticals