



COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS, INC.  
Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive  
Moraga, CA 94556-1551  
Tel: 925/283-1850  
Fax: 925/283-1850

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

Dockets Management System  
U.S. Department of Transportation  
400 Seventh Street, SW  
Washington, D.C. 20590-0001

June 27, 2000

**RE: Docket Number RSPA-99-6283 — 35**  
**HM-230**  
**RIN 2137-AD39**

Gentlemen:

The Council on Radionuclides and Radiopharmaceuticals (CORAR) supports the comments submitted by the Radiopharmaceutical Shippers and Carriers Conference (RSCC) regarding the ANPR which considers the adoption of ST-1 into the hazardous materials transportation regulations. CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

CORAR is in agreement with the points made by the RSCC with the following of particular concern:

- 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 fact that RSPA tentatively plans to make the adoption of ST-1 effective on January 1, 2002 when the IMO and ICAO will likely adopt ST-1 on July 1, 2001 poses significant problems and the potential disruption of multi-model and international shipments.
- Language of the regulations needs to be simplified and clarified, rather than further complicated, to ensure understanding by various segments of the distribution network with a wide range of educational levels.
- The passive controls already in place for maximum package, consignment and vehicle dose rates provide adequate for protection of the public. The requirements

for RPP's include actions for which compliance will not be possible to demonstrate. Categorical exemptions for distribution segments where documented doses are less than 1 mSv should be considered. The approach taken in ST-1 to monitoring is inconsistent with NRC, Agreement State and other state regulations, which require monitoring of individuals who are likely to receive an annual occupational dose equal to or greater than 5 mSv. The adoption of ST-1 should not include the requirement for RPP's and should be addressed by RSPA under a separate rulemaking.

- The provision for quality assurance programs in ST-1 should not be adopted without justification. Based on the history of performance of transportation of radioactive materials, the passive controls already in place appear to be adequate.
- The domestic Type A<sub>2</sub> limit of 20 Ci for Mo-99 should be retained with the adoption of ST-1. This is needed to allow domestic manufacturers to continue to provide Mo-99 generators to the diagnostic nuclear medicine community.
- The adoption of communications requirements of Section V of ST-1 would again impose unnecessary burdens on shippers without commensurate benefit to the safety of workers or the public. If adopted with ST-1, compliance with the requirements should be optional for the six-month interim period. The addition of the UN identification number and the letters "UN" should for excepted packages should not be adopted with ST-1.
- The placarding of "freight containers carrying packages other than excepted packages" should not be required as called for in paragraph 546. This provision is established in the domestic transport regulations and adoption of this requirement under ST-1 would not be based on any demonstrated need to improve on safety.
- The allowance for the use of strong, tight packages for domestic exclusive use transport of LSA/SCO materials needs to be retained in 173.427.
- The regulations need to be clarified as to how packages manufactured under earlier versions of SS6 will be phased out and how and if these packages would be revalidated.

CORAR appreciates the opportunity to comment on this ANPR and is willing to continue its participation in the rulemaking process. Please contact us if there should be any questions concerning these comments or the need for any additional information.

Sincerely,



Mark A. Doruff, CHP  
Council on Radionuclides and Radiopharmaceuticals, Inc.