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Council on Radionuclides and Radiopharmaceuticals, Inc.

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OFFICE  
OF  
ADJUDICATION

29 October 1999

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

DOCKET NUMBER  
PETITION RULE PRM 35-15  
(64FR45907)

Subject: Docket No. PRM-35-15: Jeffery C. Angel: Receipt of Petition for Rulemaking

Dear Sirs:

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR is a North American trade association whose members include manufacturers and distributors of diagnostic and therapeutically radiopharmaceuticals. CORAR members also operate commercial nuclear pharmacies.

CORAR opposes the proposed changes put forth in a petition for rulemaking by the Nuclear Regulatory Commission published in the Federal Register, p. 15907 dated August 28, 1999. The petition requests the elimination of the use of hand-held shields and devices for the delivery of radiopharmaceuticals by injection. It further suggests that the NRC codify that the so-called Angle Shield device be required for such use.

CORAR opposes this petition for rulemaking on the following grounds:

1. Existing shields for hand-held delivery of radiopharmaceuticals have been available and used for many years without compromising the safety of either the patient or the health professional in the delivery of such products.
2. It is not the purpose of either the Code of Federal Regulations or the NRC to endorse a specific manufacturer's product.
3. Codifying the Angel Shield as proposed in the petition would, in effect, provide a monopoly for this product.

Thank you in advance for your attention to our concerns.

Sincerely,

Robert A. Morgan, Esq.  
Chairman, CORAR

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