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DEPARTMENT OF NUCLEAR MEDICINE



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Re: Docket No. PRM-35-1(44FR 26817)

In view of the rapid developments and changes that occur in Diagnostic Nuclear Medicine procedures, a rigid or fixed rule such as that in the Federal Register with respect to the package insert (44 FR 10358, effective March 22, 1979, amendments to its regulation 10 CFR part 35) inhibits dissemination of safe and efficacious procedures. I would like to recommend that the amendments requiring the physicians to follow the package insert regarding chemical and physical form, route of administration, and dosage range, be either rescinded or modified so that new safe diagnostic procedures utilizing approved radiopharmaceuticals within the approved dosage range be available to physicians for their use based on their clinical judgement.

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Acknowledged by card 7-18-79