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DOCKET NUMBER

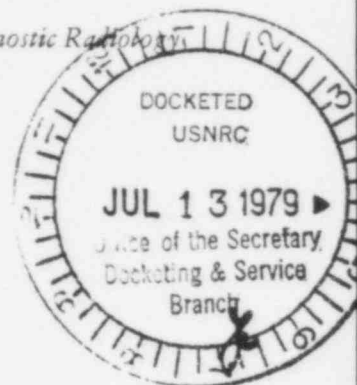
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PETITION RULE PRM - 35-1 (44FR 26817)

July 2, 1979

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C.

Attention: Docketing and Service Branch



Re: Federal Register Vol. 44. Nor. 89,
Monday, May 7, 1979. "George V.
Taplin, M.D., Filing of Petition
for Rule Making

Dear Sirs:

I strongly concur with Dr. Taplin's request that the Commission reconsider and rescind the requirement that physicians must use an approved radiopharmaceutical strictly in accord with the manufacturers package insert.

The enactment of the ruling without this modification will not only prevent useful applications of current radiopharmaceuticals but also place certain current physician practices in jeopardy.

The rule without Dr. Taplin's modification assumes that physicians who handle and administer radiopharmaceuticals are generally ignorant of dosimetry considerations or effects of administration of these agents by alternate routes. This hypothesis is incorrect. The NRC has established requirements which include extensive training in dosimetry and other aspects of radionuclide administration prior to licensing. If the NRC believes that, in spite of this, licensees are ignorant of the dosimetry considerations associated with alternative routes of administration, it should achieve improvement in this area by increasing training requirements.

The proposed regulation without Dr. Taplin's modification will prevent early useful application of techniques which involve no increased patient risk. Moreover the enforcement of the proposed rule without Dr. Taplin's modification would make virtually every clinical practitioner in nuclear medicine guilty of non-compliance.

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Acknowledged by card. 7-18-79. *wah*

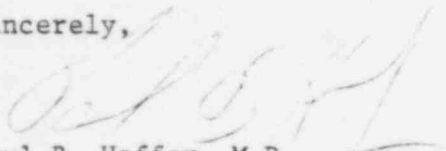
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For example it is common practice for many practitioners to give small quantities of ^{99m}Tc -Sulfur Colloid orally to define the location of the stomach. This practice would become a violation. Even accidental subcutaneous or intramuscular injection of a small amount of radiopharmaceutical during intravenous administration would constitute a violation.

I believe the proposed rule without Dr. Taplin's modification would have little benefit and great harm. Furthermore I believe it will be generally disregarded by physicians engaged in providing good medical care to their patients. If the purpose of the original rule was to remove the FDA and NRC from dictating the actual practice of medicine it would best be achieved by including Dr. Taplin's proposed modification.

Sincerely,



Paul B. Hoffer, M.D.
Professor of Diagnostic Radiology
Director, Section of Nuclear Medicine

PBH/rac

cc: George V. Taplin, M.D.

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