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COLLEGE OF MEDICINE

DEPARTMENT OF RADIOLOGY
DIVISION OF NUCLEAR MEDICINE

360

December 4, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, D.C. 20555

RE: Docket No. PRM-35-9

Dear Mr. Secretary:

I am writing in support of the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine (Docket No. PRM-35-9). I am a practicing Nuclear Medicine physician at University Medical Center, University of Arizona Health Sciences Center, Tucson. Existing Nuclear Regulatory Commission regulations in 10 CFR Parts 30, 33 and 35 place unnecessary restrictions on the practice of medicine and the practice of pharmacy, and the Petition provides remedies to those restrictions. Although Arizona is an Agreement State, the Arizona Radiation Regulatory Agency looks closely to NRC regulations for guidance, and NRC in turn evaluates the Arizona program for adequacy and compatibility, so the NRC regulations have an effect on my practice.

The Atomic Energy Act of 1954 provides, in Section 104(a): "...the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to...protect the health and safety of the public." The current NRC requirements that radiopharmaceuticals be prepared in strict accordance with manufacturers' instructions and used only for indications specified in the package insert have exactly the opposite effect of permitting the "widest amount of medical therapy possible." For example, such requirements, if literally applied, would prevent the following diagnostic procedures from being performed at my institution:

1. Imaging of parathyroid glands. The radiopharmaceutical is approved for imaging the heart, and it has become the standard agent for imaging parathyroid glands, but the package insert does not include the latter indication.

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2. Measurements of skin blood flow. This test is very useful in deciding whether an amputation is necessary and at what level it should be performed. The radiopharmaceutical is approved, a wide body of scientific knowledge has validated the technique, but the route of administration is not included in the package insert.

3. Measurements of lymphatic flow. This test is often able to demonstrate why an arm or leg is swollen and to help in determining what should be done. The radiopharmaceutical is approved, studies using the technique have been published, but the route of administration is not included in the package insert.

4. Measurements and imaging of cerebrospinal fluid flow around the brain. The radiopharmaceutical, approved for other indications, delivers a lower radiation dose than the radiopharmaceuticals that include this indication on the package insert.

Radiopharmaceuticals are regulated by the Food and Drug Administration and, under certain circumstances, by state boards of pharmacy. Regulations of FDA and the state boards adequately protect public health and safety. Investigational uses of radiopharmaceuticals are governed by radiation safety committees, constituted in accordance with NRC and agreement state regulations, and institutional review boards, constituted in accordance with 45 CFR Part 46. Additional NRC regulation restricts the practice of medicine and pharmacy, limits beneficial diagnostic (and potentially also therapeutic) procedures available to patients, but provides no incremental benefit to public health and safety.

I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking.

Sincerely,

James M. Woolfenden

James M. Woolfenden, M.D.
Professor of Radiology