

DOCKET NUMBER 35-9
PETITION RULE PRM
(54FR 38239)

Geisinger 63

October 19, 1989

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OFFICE OF THE
DOCKETING AND SERVICE
BRANCH

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, DC 20555

Dear Sir:

As Chief of the Nuclear Medicine Service of the Geisinger Medical Center, Danville, Pennsylvania, I am writing to express my support for the petition for rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The changes in 10CFR35 relating to restriction in the use of by-product material have a serious impact upon the quality of medical care that I am allowed to offer.

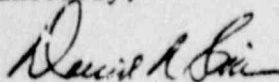
Restricting the use of by-product radiopharmaceuticals to those specifically listed in the package insert prevents the occasional, but critically important tailor-made examination to determine the physical integrity of catheters and other devices used for cancer chemotherapy, relief of chronic ascites or hydrocephalus, and other indications. Moreover, it precludes the evaluation of the physiology of a variety of organs such as the stomach in children and adults with chronic vomiting and the bladder in children with chronic renal wasting disease. Alternative techniques are more expensive, require more radiation, are more invasive, are less accurate or combine several of the foregoing disadvantages.

Although one normally observes expiration dates, certain emergency situations arise where a delay caused by recompounding or reordering a radiopharmaceutical is clearly harmful to a patient's well-being. The latitude to stretch this within reasonable limits can occasionally save lives.

The package insert required by the FDA is not intended to restrict but to guide. Ultimately, it is the physician, not the NRC, that has the fiduciary responsibility to the patient. By thus prescribing what may and may not be done, the NRC has taken on the role of practicing medicine, in contradiction of its own long-standing policy.

In closing, I ask that the NRC rescind these burdensome and unnecessary provisions.

Sincerely,



David R. Brill, M.D.

DRB:dme

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