



EMORY UNIVERSITY SCHOOL OF MEDICINE
(54FR38234) DEPARTMENT OF RADIOLOGY

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DIVISION OF NUCLEAR MEDICINE
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Secretary of the Commissioner
US Nuclear Regulatory Commission
Docketing and Service Branch
Docket # PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

As a practicing Nuclear Medicine physician, I am strongly in favor of the petition for rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revised 10CFR35 regulations (effective April, 1987) which deal with the medical use of by-product materials are difficult to comply with and maintain high quality nuclear medicine practice which is the best interest of the patient.

The revised regulations are in conflict with FDA policy regarding radioactive substances which we use every day in the practice of Nuclear Medicine. For example, we have been doing C-14-urea breath tests for identification of campylobacter gastritis, an organism implicated in the cause of peptic ulcer disease. Recently it has become apparent that the Nuclear Regulatory Commission, in insisting upon compliance with 10CFR35, has said that C14 Urea cannot be used because it is not an IND or NDA radiopharmaceutical. We checked with the FDA prior to instituting this test at our institution and we were told by the FDA that under the rules of practice of medicine and pharmacy we could utilize this material for clinical purposes. The radioactivity (0.5 microcurie of C-14) is very minimal and not of any concern for a patient referred for this test. But, because of the conflict with 10CFR35, we apparently can no longer utilize this clinically effective test without securing an IND. From the perspective of a practicing physician trying to do what is best for the patient, it seems that the NRC is interfering with the practice of medicine.

In other instances, the regulatory provisions in part 35 do not allow practices which are legitimate under FDA regulations and State medicine and pharmacy laws. I don't believe that the NRC really intends to interfere with the safe practice of medicine. Therefore, I strongly urge that the NRC adopt the ACNP-SNM petition for rulemaking as soon as possible.

Sincerely,

Naomi P. Alazraki, M.D.
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Professor of Radiology
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