



EMORY UNIVERSITY SCHOOL OF MEDICINE

DEPARTMENT OF RADIOLOGY

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DIVISION OF NUCLEAR MEDICINE  
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PETITION RULE PRM 35-9  
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OFFICE OF  
DOCKETING  
BRANCH

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

Dear Mr. Secretary:

I am a practicing Nuclear Medicine physician and I am strongly in favor of the petition for rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. Compliance with the revised 10CFR35 regulations which deal with the medical use of by product materials would be extremely difficult while trying to maintain high quality nuclear medicine practice in the best interest of the patient. The regulatory provisions in part 35 does not allow practices which are legitimate under FDA regulations and state medicine and pharmacy laws. The revised regulations are in conflict with FDA policy regarding radioactive substances which we use daily in our practice.

For example, we have be doing C-14-urea breath tests for identification of gastric colonization with campylobacter pylorii, an organism implicated in causing peptic ulcer disease. With the new guidelines, insisting on compliance with 10CFR35, the C-14-urea breath test cannot be used because it is neither an IND nor NBA radiopharmaceutical. Prior to performing this test at our institution, the FDA reported that under the rules of practice of medicine and pharmacy that we could utilize this material for clinical purposes. The radioactivity (0.5 microcurie of C-14) is minimal. However, because of the new conflict with 10CFR35 we can no longer utilize this clinically effective test without securing an IND. From the perspective of a practicing Nuclear Medicine physician, the NRC guidelines substantially interfere with the practice of medicine aimed at non-invasive diagnosis in the best interest of the patient.

I hope that the NRC does not intend to interfere with the safe practice of medicine. I strongly urge that the NRC adopt the ACNP-SNM petition for rulemaking as soon as possible.

Sincerely,

Jack Ziffer, Ph.D., M.D.  
Assistant Professor Radiology

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