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Secretary of the Commission
U.S. Nuclear Regulatory Comission
Washington, DC 20555
Attention: Docketing and Services Branch
Docket No. PRM-35-9

Dear Secretary:

On behalf of the over 25,000 physician and physicist members of the American College of Radiology (ACR), we support implementation of the petition for rulemaking submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) published in the Federal Register on September 15, 1989 (54 FR 38239).

The ACR is committed to the safe and efficacious use of by-product materials in rendering quality patient care. As originally written, 10 CFR Part 35 confines the use of NDA (New Drug Applications) or IND (Investigational New Drug Applications) drugs to the instructions contained in the package insert. Strict enforcement of the regulation unnecessarily restricts physician discretion to perform necessary procedures. Such a situation, for example, may prohibit the physician from rendering necessary services to children or pregnant women because the package insert does not permit such use. The rule also limits the application of radiopharmaceuticals to only those uses which are specifically indicated in the package insert, further eroding the physician's discretion to perform medically necessary services.

By adopting the various recommendations develcped in the petition, the Commission would restore clinical decision making for the use of radiopharmaceuticals to the physician. The physician would still be constrained by peer review and the prospect of malpractice, but would now be able to deliver necessary care using sound clinical judgment.

The ACR appreciates the opportunity to comment on the ACNP-SNM petition for rulemaking concerning the expansion in scope and discretion in rendering necessary patient care. If you have any questions please contact me.

Sincerely,

Otha W. Linton

Otha W. Linton
Associate Executive Director

OWL/pgm

cc: C. Douglas Maynard, M.D.

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