

Mallinckrodt Medical, Inc.

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

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DOCKETING & SERVICE
BRANCH

Dear Mr. Secretary:

In June 1989, the Society of Nuclear Medicine ("SNM") and the American College of Nuclear Physicians ("ACNP") jointly filed a petition for a rule making change ("Petition") which would modify NRC's existing Part 35 Medical Use regulations that currently: 1) limit physicians to the use of only IND/NDA approved radiopharmaceuticals; 2) require strict adherence to manufacturers' instructions for elution of generators and preparation of kits; and 3) limit physicians to FDA-approved indications and routes of administration as described in the package insert for therapeutic radiopharmaceuticals.

Mallinckrodt supports the Petition as filed by the SNM and ACNP. We urge its adoption by the NRC. Adoption of this proposal would amend NRC regulations to be supportive of good medical practice as the regulations would be consistent with presently accepted nuclear medical practice.

As a manufacturer of radiopharmaceuticals used in the practice of nuclear medicine, Mallinckrodt has a very real interest in the promulgation of sound regulations reflecting those proposed by the Petition.

Very truly yours,

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