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DEPARTMENT OF RADIOLOGY
DIVISION OF NUCLEAR MEDICINE

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October 30, 1989

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

Dear Mr. Secretary:

I am writing to express my concern over the revised 10CFR35 regulations governing the medical use of byproduct materials and to support the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine in this regard.

Long experience in the field of nuclear medicine and in the administration of radioactive materials to patients for both diagnosis and therapy has impressed upon me the need for flexibility in the use of radiopharmaceuticals with regard to indications, administered amounts (within limits) etc.

In a variety of therapeutic administrations, particularly those dealing with the administration of radioiodine in thyroid cancer, careful dosimetry determinations that we perform routinely before administering radioiodine, have made it very clear that maximum therapeutic effects for patients with metastatic thyroid cancer can be achieved only with careful administration of amounts of radioiodine that are related directly to the radiation dose received by the patient's tumor and the limiting dose received by the blood and bone marrow rather than arbitrary fixed administered amounts of radioiodine.

PS/0

With regard to diagnostic administrations, the important goal of obtaining high quality diagnostic information is the overriding objective particularly in view of long experience which has never demonstrated any deleterious effects from such administrations of radionuclides. If this concern is the NRC's reason for making these changes, then before any changes are made, it seems appropriate to obtain evidence from an examination of such administrations as to the presence of deleterious effects. Extensive studies carried out in a number of areas, particularly that of radioiodine administration for thyroid diagnosis (including 20 year follow-up of routine administration of large amounts (50 to 100 uCi) of 131-I for thyroid imaging) have not shown any significant deleterious late effects (Holm et al, JNCI 84:302-306, 1989).

I feel that the changes proposed in the revised 10CFR35 regulations will be detrimental to the care of patients and I strongly urge that the NRC adopts the above mentioned petition for rulemaking.

Sincerely yours,

David V. Becker, M.D.
Professor of Radiology & Medicine
Director, Division of Nuclear Medicine

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