ALAN CRANSTON
CALIFORNIA

United States Senate

WASHINGTON, DC 20510

November 27, 1989

To:

Congressional Liaison
Nuclear Regulatory Commission
1717 H Street, N.W.
Washington, D.C. 20555

Enclosure From:

Malcolm R. Powell, M.D.
Associate Clinical Professor of Medicine
University of California at San Francisco
350 Parnassus Avenue, Suite 908
San Francisco, California 94117

Re:

Please address the concerns raised by Dr. Powell regarding regulations on nuclear medicine

I forward the attached for your consideration.

Your report, in duplicate, along with the return of the enclosure will be appreciated.

Sincerely,

Alan Cranston

Please address envelope to:
Senator Alan Cranston
Senate Office Building
Washington, D.C. 20510

Att:

Karen Butler, 202/224-3553

NMC NUCLEAR MEDICINE CONSULTANTS
A SAN FRANCISCO BAY AREA MEDICAL GROUP

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October 17, 1989

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

Dear Mr. Secretary:

This is written to express strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am practicing nuclear medicine physician at the above-captioned outpatient clinic and also at Alameda Hospital and another outpatient clinic in Marin County. Our nuclear medicine group is deeply concerned over the revised 10 CFR 35 regulations effective April 1987. These regulations significantly impact upon the medical use of byproduct material and interfere with my ability to practice highest quality nuclear medicine. The current regulatory provisions in part 35 (35.100, 35.200, 35.300, and 33.17(a)(4)) do not allow practices which are legitimate and legal under FDA regulations and state medicine and pharmacy laws. The NRC functions to prohibit any deviation of kit utilization different from the applications described in package inserts while the FDA does allow and often encourages other clinical uses of approved drugs. The actions of the NRC are totally inappropriate in addition because the drugs under consideration are used in true pharmacologic tracer doses wherein the diagnostic: toxic ratios are much higher than the therapeutic: toxicity ratios commonly encountered with therapeutic drugs The NRC restrictive attitude will therefore adversely affect public health by restricting access to appropriate nuclear medicine procedures, exposing patients to higher radiation absorbed doses from alternative legal but non-optimal studies and by exposing hospital personnel to higher radiation absorbed doses because of unwarranted repetitive procedures.

I would encourage the NRC not to strive to construct proscriptive regulations covering all aspects of medicine. I would encourage the NRC to rely on the expertise of the FDA, the State Boards of Pharmacy, the State Boards of Medical Quality Assurance, and the Joint Commission on Accreditation of Healthcare Organizations as well as their radiation safety committees and institutional Q/A review procedures. Most important, I would encourage the NRC to rely upon the professional judgement of physicians and pharmacists who have been well trained to administer and prepare these materials.

In summary, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely, ~~89 10 25 033~~ 2 PP

Malcolm R. Powell M.D.

Malcolm R. Powell, M.D.
Associate Clinical Professor of Medicine, University of California, San Francisco
Fellow American College of Physicians

1. DIPLOMATE, AMERICAN BOARD OF NUCLEAR MEDICINE
2. DIPLOMATE, AMERICAN BOARD OF INTERNAL MEDICINE
3. DIPLOMATE, AMERICAN BOARD OF ENDOCRINOLOGY & METABOLIC DISEASES
4. MEMBER, AMERICAN THYROID ASSOCIATION

E. William Allen, M.D., President, ACNP
Richard A. Holmes, President, SNM
The Honorable Barbara Boxer, US House of Representatives, Washington, DC 20515
The Honorable Nancy Pelosi, US House of Representatives, Washington, DC 20515
The Honorable Alan Cranston, US Senate, Washington, DC 20510
The Honorable Pete Wilson, US Senate, Washington, DC 20510