UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 16, 1990

The Honorable Bob Stump
Member, United States House of
Representatives
5001 Federal Building
Phoenix, Arizona 85025

Dear Congressman Stump:

This is to acknowledge receipt of your letter dated January 2, 1990, transmitting correspondence from your constituents, Mr. James J. Burnis and Dr. Richard J. Peterson, in support of a petition for rulemaking to revise 10 CFR 35 Regulations.

The petition for rulemaking was submitted to the Nuclear Regulatory Commission (NRC) by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petitioners requested that the NRC modify current regulations to allow: (a) the use of radiopharmaceuticals for therapeutic indications not listed in the package insert (diagnostic indications are not restricted by current regulations), (b) deviations from the manufacturer's instructions in preparing radiopharmaceuticals, and (c) compounding radiopharmaceuticals from reagent chemicals.

The NRC published a Federal Register notice (54 FR 38239, September 15, 1989), announcing receipt of the petition and providing a 90-day public comment period. We have received more than 400 comment letters.

In light of the information submitted by the petitioners and the commenters, the NRC is currently reexamining its regulations governing the use of radiopharmaceuticals in nuclear medicine. The issues raised will be addressed in a rulemaking proceeding specifically designed to resolve the petition. During this rulemaking process, the NRC will consult with the Food and Drug Administration, which approves the package inserts and the manufacturer's instructions, and the State Boards of Pharmacy and invite their views regarding the resolution of this petition.

I want to assure you that the comments of your constituents will be considered along with the others in reexamining our regulations. However, it would be premature to predict the outcome of the reexamination before completion of the rulemaking proceeding.

I trust this information is responsive to your request.

Sincerely,

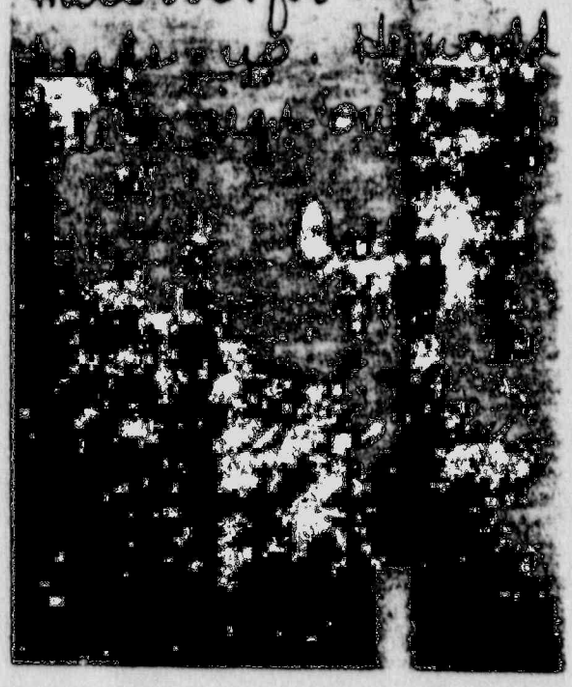
Edward Fay

Dennis K. Rathbun, Director
Congressional Affairs
Office of Governmental and
Public Affairs

CCS2
1/1

Mr. Blaha -

Dennis Rathbun brought these over for OEDO's [illegible]. He would [illegible]



Letter also verbally approved by Jim Blaha and Mike Weber (per Dennis Rathbun/Betsy Keeling) on 1-11-90.

[redacted]

Congress of the United States
House of Representatives
Washington, D.C. 20515

January 2 1990

TO: CONGRESSIONAL LIAISON
Mr. Dennis Rathbun
Director, Congressional Affairs
U.S. Nuclear Regulatory Comm.
Washington, DC 20555

REF:

[redacted]

Burnis and Peterson
RE: American College of Nuclear
Sir: Physicians petition for
rulemaking

The attached communication is sent for your consideration. Please investigate the statements contained therein and forward me the necessary information for reply.

Yours truly,

BOB STUMP, M.C.
Third District, Arizona

PLEASE RETURN TO:
5001 Federal Building
Phoenix, Arizona 85025
Attn: Bruce Bartholomew

[redacted]

9001160240

W. RANSOM KELLEY, M.D., F.A.C.R.
ROBERT F. GREEN, M.D., F.A.C.R.
RICHARD W. VANBUSKIRK, M.D.
MICHAEL R. GEYSER, M.D.
DONALD TRAICOFF, M.D.
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EDWARD J. WICKMAN, M.D.

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STUART B. COHEN, M.D.
MICHAEL KORNREICH, M.D.
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THOMAS E. McCALL, M.D.
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RICHARD J. PETERSEN, M.D.

ASSOCIATED RADIOLOGISTS, LTD.
450 WEST FIFTH PLACE
MESA, ARIZONA 85201
PHONE (602) 969-3537

DIAGNOSTIC IMAGING

November 29, 1989

The Honorable Bob Stump
230 North First Avenue
Phoenix, Arizona 85003

Dear Representative Stump:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine physician at Desert Samaritan, Mesa Lutheran and Valley Lutheran hospitals in Mesa, Arizona. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

Currently, the 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. These regulations therefore inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternative legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not strive to construct proscriptive

(Continued)

regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, the professional judgment of physicians and pharmacists who have been well-trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCPP, to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

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

Sincerely,

Richard J. Petersen, M.D.
FACNP, FACR

RJP:mc

Lutheran Healthcare Network

Valley Lutheran Hospital
6644 Baywood Avenue
Mesa, Arizona 85206
(602) 981-2000

November 30, 1989

Congressman Robert Stump
230 N. 1st Avenue
Phoenix, Az

Dear Congressman Stump:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine technologist at Valley Lutheran Hospital in Mesa, Arizona. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications; on the contrary, such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economic incentive to do so.

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

Sincerely,

James J. Burnis

James J. Burnis, CNMT
Valley Lutheran Hospital

JJB/bg
cc: Senator Dennis DeConcini
Senator John Mc Cain
Congressman John J. Rhodes, III.
Congressman Robert Stump
Congressman Jon Kyl