

NATIONAL ASSOCIATION OF VETERANS AFFAIRS CHIEFS OF NUCLEAR MEDICINE

169

DOCKET NUMBER
November 1, 1989
PETITION RULE PRM 35-9
(54 FR 38239)
'89 NOV -8 P4:31
OFFICE OF THE SECRETARY
DOCKETING & SERVICE
BRANCH

Re: Petition for Rulemaking 10 CFR Parts 30, 33 and 35
(Docket #PRM-35-9)

Dear Mr. Chilk:

The National Association of VA Chief of Nuclear Medicine (NAVACNM) recommends that the NRC adopt the petition for rule making submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) of June 5, 1989.

NAVACNM is an organization of practicing nuclear medicine physicians who are responsible for the nuclear medicine aspects of care of our nations veterans. We are convinced that current NRC's existing Part 35 Medical Use regulations limit physicians' to the use of only IND and NDA approved radiopharmaceuticals, demand strict adherence to manufacturer's instructions for the elution of generators and preparation of kits, permit only FDA-approved indications and routes of administration as detailed by the package insert for therapeutic radiopharmaceuticals, thus, ignoring the scope of the practice of nuclear medicine. We believe that NRC regulations must allow Nuclear Medicine physicians to prepare and prescribe radiopharmaceuticals differently from manufacturers' recommendations so as to permit appropriate diagnostic and therapeutic applications as dictated by individual patient needs.

NAVACNM

President

Milton Gross, M.D.
ANN ARBOR, MI

Secretary-Treasurer

Frederick C. Petty, M.D.
TEMPLE, TX

Executive Committee

Naomi Alazraki, M.D.
DECATUR, GA

Marvin B. Cohen, M.D.
SEPULVEDA, CA

G.T. Krishnamurthy, M.D.
PORTLAND, OR

Nicholas Kutka, M.D., Ph.D.
HOUSTON, TX

Johnny W. Scott, M.D.
BIRMINGHAM, AL

Donald E. Tow, M.D.
W. ROXBURY, MA

President-elect

Tuhin K. Chaudhuri, M.D.
SAN ANTONIO, TX

Past Presidents

Rex B. Shafer, M.D.
MINNEAPOLIS, MN

Richard A. Holmes, M.D.
COLUMBIA, MO

William H. Blahd, M.D.
LOS ANGELES, CA

8911150229 891101
PDR PRM PDR
35-9

P.O. BOX 1633
TEMPLE, TEXAS 76503

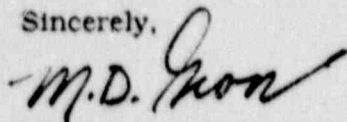
DS10

We fully agree and support this petition which seeks to change the regulatory language to prepare and use radiopharmaceutical "in accordance with FDA regulations". 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 present FDA regulations and individual state medical and pharmacy statutes. These highly restrictive NRC regulations will bias against new and innovative uses of radiopharmaceuticals and will result in reliance on older and less efficacious techniques.

The NRC has become inappropriately involved in the professional activities of nuclear medicine physicians and we feel that as nuclear medicine professionals we must be able to exercise our professional judgement and acumen as appropriate to assure optimal patient care.

The NAVACNM fully supports the ACNP/SNM petition for rule making and urges the expeditious adoption of this proposal.

Sincerely,



MILTON D. GROSS, M.D.
Professor of Internal Medicine
Department of Internal Medicine
Division of Nuclear Medicine
University of Michigan Medical Center
Chief/Deputy Director, Nuclear Medicine, Region IV
Department of Veterans Affairs
President, NAVACNM

MDG:lcb

cc: J. Fletcher, M.D.
NAVACNM Executive Committee